

Navigated Instrument System

for use with

Reform[®] Pedicle Screw System
Reform *Ti* Pedicle Screw System
Reform MC Midline Cortical Screw System
SureLOK[™] MIS 3L Percutaneous Screw System
Reform *Ti MIS CT Modular* Percutaneous Screw System



For manual calibrated use with the Medtronic
StealthStation[™] Surgical Navigation System

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NAVIGATED INSTRUMENT SYSTEM OVERVIEW

The Navigated Instrument System is designed for compatibility of the Precision Spine screw systems with the Medtronic StealthStation™ Navigation System and the NavLock™ Trackers.

DEVICE DESCRIPTION

The Navigated Instrument System is comprised of subsets of instruments intended to be used in conjunction with the StealthStation Navigation System by Medtronic Navigation, Inc. “Medtronic Navigation” to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement. The Navigated Instruments are comprised of Bone Awls, Bone Taps, Bone Probes, Drills, Drill Guides (not navigated), and Screw Drivers.

The Navigated Instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S7 Orange, Violet, and Green NavLock Tracker (Part Numbers 9734683, 9733482, 9734734), and StealthAir™ Spine Frame (Part Number 9735249) while utilizing the Synergy Spine and Trauma Software for StealthStation S7 (Software Version 2.1.0) “Open Thoracolumbar Fusion” procedure. The products are supplied clean and “NON-STERILE”.

INDICATIONS

The Navigated Instruments are indicated for use during the preparation and placement of Precision Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigated Instruments are reusable and are specifically designed for use with the Medtronic Navigation StealthStation System which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. Use of the Navigated Instrument System is limited to use only with Reform®, Reform® HA, and SureLOK™ Spinal Fixation Systems.

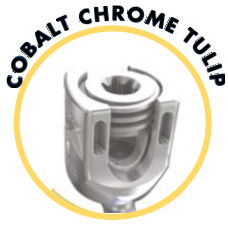
Please refer to the following Instructions For Use (IFU) and Surgical Techniques for complete system guides, descriptions, indications and warnings:

- Reform Pedicle Screw System
- Reform Ti Pedicle Screw System
- Reform MC Midline Cortical Screw System
- SureLOK MIS 3L Percutaneous Screw System
- Medtronic StealthStation Navigation System

PRECISION SPINE SCREW SYSTEMS OVERVIEW

Reform® Pedicle Screw System

Non-Cannulated • Reduction • HA • Uniplanar • Uniplanar Reduction • MIS Uniplanar Reduction
Modular Tulips • Modular Reduction Tulips



Reform Ti Pedicle Screw System

Non-Cannulated • Cannulated • HA • Modular Tulips



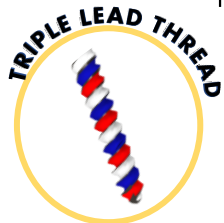
Reform MC Midline Cortical Screw System

Non-Cannulated • Cannulated • Modular 4.75mm & 5.5mm Tulips



SureLOK™ MIS 3L Percutaneous Screw System

Integrated Reduction • Percutaneous Rod Insertion • Internal Rod Reduction



Reform Ti MIS CT Modular Percutaneous Screw System

Modular Tulip & Bone Screws • Percutaneous Rod Insertion • Integrated Reduction



NAVIGATION INSTRUMENTATION

Bone Awl
Bone Awl, Cannulated

70-RF-0001
70-3L-0001



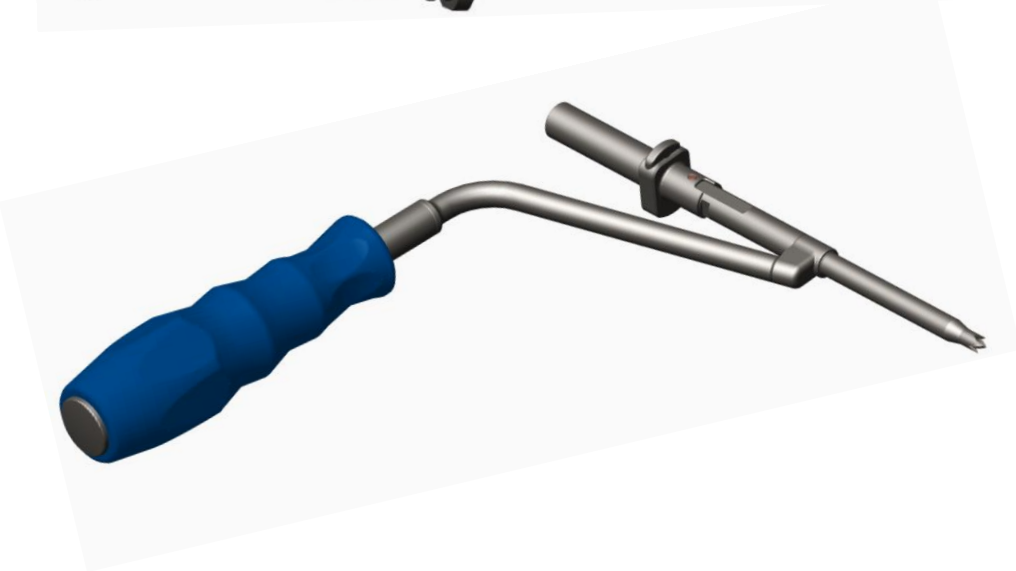
Lenke Probe

70-RF-0003



Reform® MC Midline Cortical Drills
Reform MC Drill Guide (*not navigated*)

70-MC-0445 to 70-MC-0465
70-MC-0040



INSTRUMENTATION

Reform®/Reform Ti Taps, Non-Cannulated
 Reform HA Taps, Non-Cannulated
 Reform MC Midline Cortical Taps, Non-Cannulated
 SureLOK™ MIS 3L/Reform Ti Taps, Cannulated

70-RF-0545 to 70-RF-0595
 70-RH-1045 to 70-RH-1095
 70-MC-0545 to 70-MC-0595
 70-3L-0555 to 70-3L-0595



Reform Polyaxial Driver, Non-Cannulated, T20 (Black Sleeve)	70-RF-0700
Reform Ti Polyaxial Driver, Non-Cannulated, T25 (Green Sleeve)	70-RT-0720
Reform Ti Polyaxial Driver, Cannulated, T25 (Green Sleeve)	70-RT-1720
Reform MC Polyaxial Driver, Non-Cannulated, T25 (Blue Sleeve)	70-MC-0700
Sure-LOK MIS 3L Polyaxial Driver, Cannulated, 3.5mm Hex (Silver, Short Sleeve)	70-3L-0700
Reform Ti MIS CT Polyaxial Driver, Cannulated, T25 (Gold Knob)	70-RT-1750



70-RF-0700: Black Sleeve



70-RT-0720, 70-RT-1720: Green Sleeve



70-MC-0700: Blue Sleeve



70-3L-0700: Silver, Short Sleeve



70-RT-1750: Gold Knob

INSTRUMENTATION

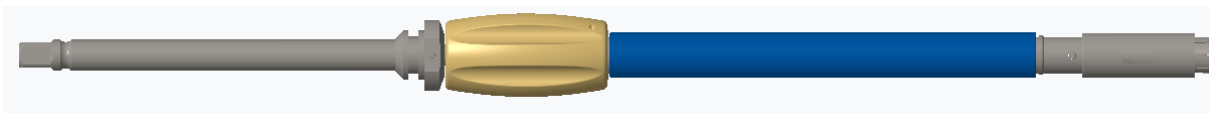
Reform® Modular Driver, Non-Cannulated, T20 (<i>White Sleeve</i>)	70-RM-0800
Reform Ti/MC Modular Driver, Non-Cannulated, T25 (<i>Blue Sleeve</i>)	70-MC-0800
Reform Ti/MC Modular Driver, Cannulated, T25 (<i>Blue Sleeve</i>)	70-MC-1800
Reform Ti/MC Modular Driver, Cannulated T25 (<i>Right Hand Tighten, Gold Knob, Blue Sleeve</i>)	70-MC-1820*



70-RM-0800: White Sleeve

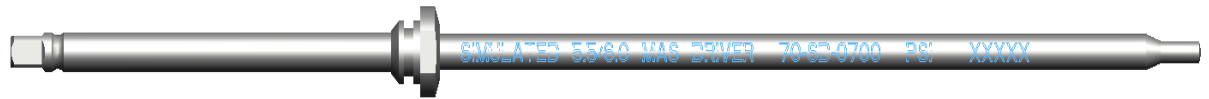


70-MC-0800, 70-MC-1800: Blue Sleeve



70-MC-1820*: Gold Knob, Blue Sleeve

Simulated 5.5/6.0 MAS Driver	70-SD-0700
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* SPECIAL ORDER

SET CONFIGURATION

Reform®, Reform Modular, Reform HA

Reform, NON-CANNULATED

70-BK-0100

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-RF-0545	4.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0555	5.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0565	6.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0575	7.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0585	8.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0595	9.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0700	Reform Polyaxial Driver, Non-Cannulated, T20	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform Modular, NON-CANNULATED

70-BK-0101

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-RF-0545	4.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0555	5.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0565	6.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0575	7.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0585	8.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0595	9.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RM-0800	Reform Modular Driver, Non-Cannulated, T20	2
70-RF-0700	Reform Polyaxial Driver, Non-Cannulated, T20	1
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform HA, NON-CANNULATED

70-BK-0102

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-RH-1045	4.5mm Reform HA Tap, Non-Cannulated	1
70-RH-1055	5.5mm Reform HA Tap, Non-Cannulated	1
70-RH-1065	6.5mm Reform HA Tap, Non-Cannulated	1
70-RH-1075	7.5mm Reform HA Tap, Non-Cannulated	1
70-RH-1085	8.5mm Reform HA Tap, Non-Cannulated	1
70-RH-1095	9.5mm Reform HA Tap, Non-Cannulated	1
70-RF-0700	Reform Polyaxial Driver, Non-Cannulated, T20	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform Ti, NON-CANNULATED

70-BK-0103

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-RF-0545	4.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0555	5.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0565	6.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0575	7.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0585	8.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0595	9.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RT-0720	Reform Ti Polyaxial Driver, Non-Cannulated, T25	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform Ti, CANNULATED

70-BK-0104

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-3L-0555	5.5mm SureLOK™ MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0565	6.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0575	7.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0585	8.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0595	9.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-RT-1720	Reform Ti Polyaxial Driver, Cannulated, T25	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform Ti Modular, NON-CANNULATED

70-BK-0105

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-RF-0545	4.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0555	5.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0565	6.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0575	7.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0585	8.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-RF-0595	9.5mm Reform/Reform Ti Tap, Non-Cannulated	1
70-MC-0800	Reform Ti/MC Modular Driver, Non-Cannulated, T25	2
70-RT-0720	Reform Ti Polyaxial Driver, Non-Cannulated, T25	1
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

Reform Ti Modular, CANNULATED

70-BK-0106

Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-3L-0555	5.5mm SureLOK™ MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0565	6.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0575	7.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0585	8.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0595	9.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-MC-1800 70-MC-1820*	Reform Ti/MC Modular Driver, Cannulated, T25	2
70-RT-1720	Reform Ti Polyaxial Driver, Cannulated, T25	1
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

*** SPECIAL ORDER: 70-MC-1820 Reform Ti/MC Modular Driver, Cannulated T25 RIGHT HAND THREADED**

Reform MC and MC Hybrid		70-BK-0107
Item No.	Description	Qty/Set
70-RF-0001	Awl	1
70-RF-0003	Lenke Probe	1
70-MC-0445	2.7mm Drill (for 4.5mm screw)	1
70-MC-0450	3.2mm Drill (for 5.0mm screw)	1
70-MC-0455	3.7mm Drill (for 5.5mm screw)	1
70-MC-0465	4.7mm Drill (for 6.5mm screw)	1
70-MC-0400	MC Drill Guide	1
70-MC-0545	4.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0550	5.0mm Reform MC Tap, Non-Cannulated	1
70-MC-0555	5.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0565	6.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0575	7.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0585	8.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0595	9.5mm Reform MC Tap, Non-Cannulated	1
70-MC-0800	Reform Ti/MC Modular Driver, Non-Cannulated, T25	2
70-MC-0700	Reform MC Midline Cortical Polyaxial Driver, Non-Cannulated, T25	1
70-RT-0720	Reform Ti Polyaxial Driver, Non-Cannulated, T25	1
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

SET CONFIGURATION

SureLOK™ MIS 3L

SureLOK MIS 3L

70-BK-0108

Item No.	Description	Qty/Set
70-3L-0001	Awl, Cannulated	1
70-3L-0555	5.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0565	6.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0575	7.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0585	8.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0700	SureLOK MIS 3L Polyaxial Driver, Cannulated 3.5mm Hex	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

SET CONFIGURATION

Reform® Ti MIS CT

Reform Ti MIS CT

70-BK-0109

Item No.	Description	Qty/Set
70-3L-0001	Awl, Cannulated	1
70-3L-0555	5.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0565	6.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0575	7.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-3L-0585	8.5mm SureLOK MIS 3L/Reform Ti Tap, Cannulated	1
70-RT-1750	Reform Ti MIS CT Polyaxial Driver, Cannulated, T25	2
70-SD-0700	Simulated 5.5/6.0 MAS Driver	1

SURGICAL TECHNIQUE

1

PRELIMINARY SETUP

1. SPINE & TRAUMA

- Turn on StealthStation™ and log in
- Confirm Synergy Experience (Version 2.1.0) is loaded on StealthStation S7
- Select **“SPINE & TRAUMA”** to start setup for spine navigation (Figure 1)

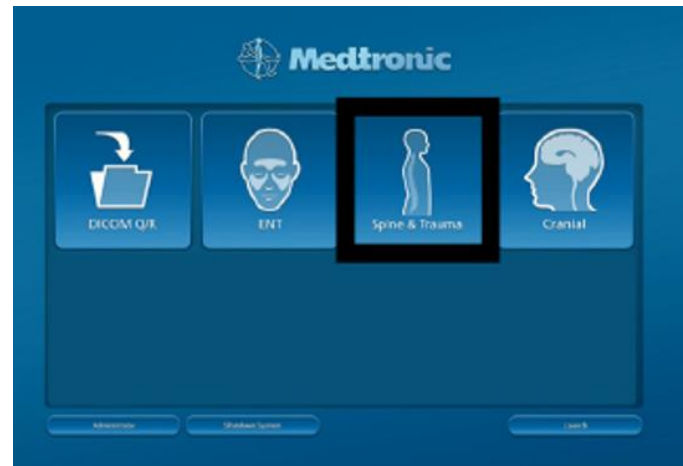


Figure 1

2. SURGEON PROFILE

- Select the desired surgeon profile from the **“SURGEON PROFILE”** tab (Figure 2).

Please note that several surgeon profiles may be listed

- Right Arrow proceeds to the next screen
- Left Arrow brings back to the previous screen

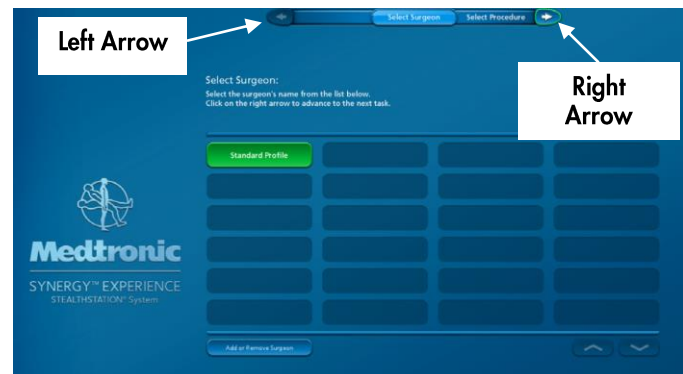


Figure 2

3. SELECT PROCEDURE

- Select the desired procedure from the **“SELECT PROCEDURE”** tab (Figure 3).
- Please note that more or less procedures may be listed*
- Click the Right Arrow to proceed to **“SETUP EQUIPMENT”**



Figure 3

SURGICAL TECHNIQUE

1 PRELIMINARY SETUP (continued)

4. SETUP EQUIPMENT

- Ensure that all necessary equipment (monitors, O-arm, etc.) are connected to the StealthStation™ (Figure 4). If lines are dashed orange, check connections/cables.

SOLID GREEN - Connected
DASHED ORANGE - Not Connected

- Click the Right Arrow to proceed to “**VERIFY INSTRUMENTS**”

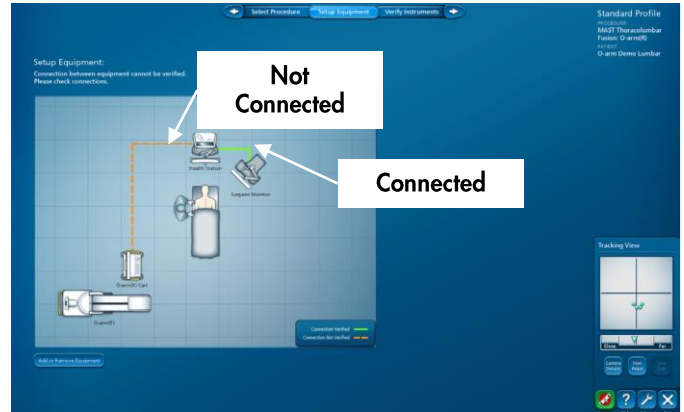


Figure 4

2 TOOL CARD ASSIGNMENT

1. VERIFY INSTRUMENTS

- The StealthStation “**VERIFY INSTRUMENTS**” screen includes “**TOOL CARDS**” that identify various navigated instruments and reference frames that may be selected for use.

Fourteen tool cards are shown on the “**VERIFY INSTRUMENTS**” Screen (Figure 5).

- Confirm that the correct reference frame is present and that others that will not be used are removed from the present session.

Reference Medtronic manual guides for further instructions.

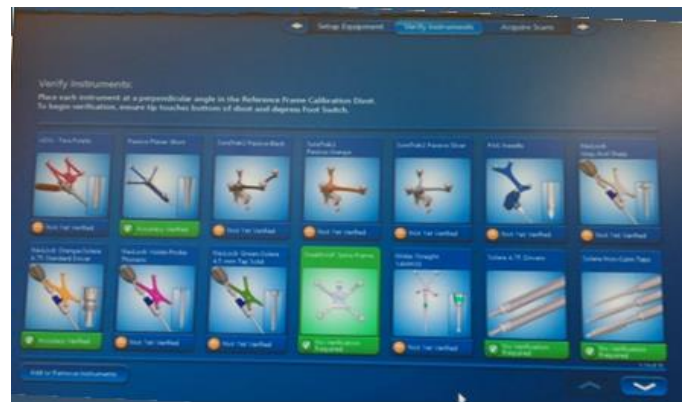


Figure 5

SURGICAL TECHNIQUE

2

TOOL CARD ASSIGNMENT (continued)

2. TOOL CARD ASSIGNMENT

- Each navigated instrument must be assigned to an appropriate Tool Card (Table 1 & Figure 6)

Tool Card	Entire Tool Card Color	Bottom Tool Card Color
Non-Verified NavLock™ Instrument	BLUE	Not Yet Verified
Verified NavLock Instrument	BLUE	Accuracy Verified
Pre-Calibrated Instrument	BLUE	No Verification Required
Reference Frame	GREEN	No Verification Required

Table 1

DO NOT USE: NON-NAVLOCK INSTRUMENT TOOL CARDS

DO NOT USE: PRE-CALIBRATED TOOL CARDS

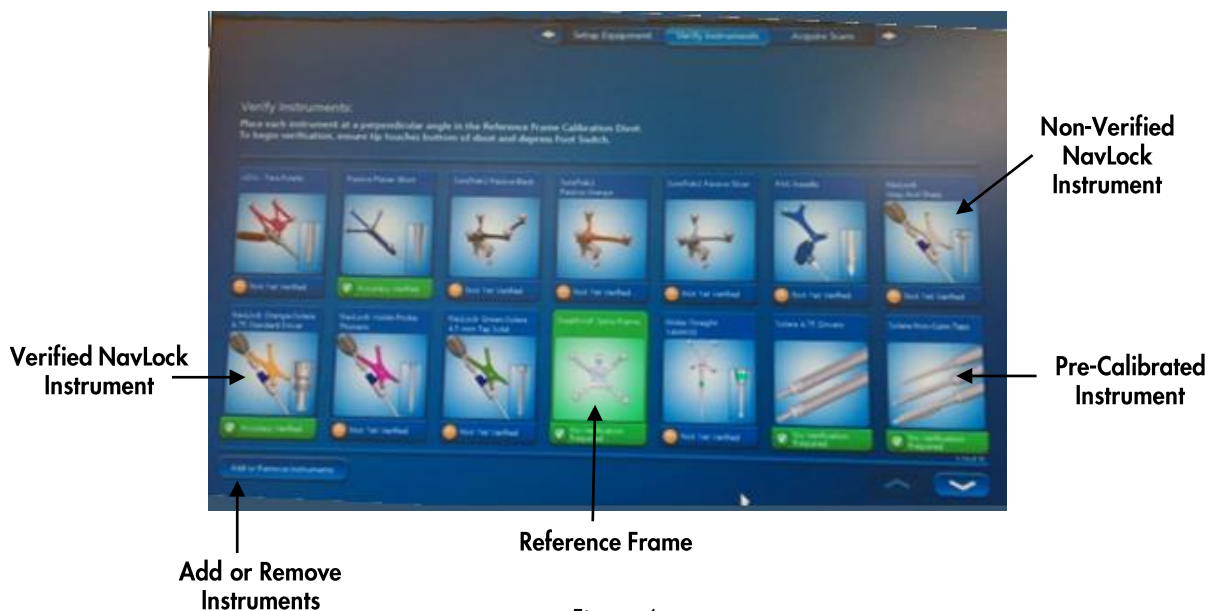


Figure 6

SURGICAL TECHNIQUE

2

TOOL CARD ASSIGNMENT (continued)

MISSING TOOL CARDS

- Some Tool Cards may not currently be included in the Instruments tab.

To add new Tool Cards:

- Select the **"Add / Remove Instruments"** button on the **"VERIFY INSTRUMENTS"** screen (Figure 6)
- A new screen, **"Add or Remove Instruments"**, will open
- Select the **"Add/Remove at this Site"** at the bottom left
- **"Instruments at this Site"** screen will open (Figure 7)
- Missing Tool Cards are listed as **"Instruments not at this site"**
- Utilize Tables 2 and 3 to find the appropriate Tool Card to add for the corresponding Precision Spine Navigated Instrument

Reference Medtronic manual guides for further instructions to add these Tool Cards.



Figure 7

SURGICAL TECHNIQUE

2

TOOL CARD ASSIGNMENT (continued)

TABLE 2: Precision Spine Navigated Instrument and Medtronic StealthStation™ Tool Card Cross Reference

(Array color assignments may differ from those depicted below. Ensure the arrays are attached to the assigned instruments.)

Part Number	Description	Corresponding Required Tool Card
Awls		
70-RF-0001	Reform®, Reform Ti, Reform MC Awl (4.0mm Diameter)	NavLock™ - Awl Sharp (requires verification) 
70-3L-0001	SureLOK™ 3L, Reform Ti MIS CT Awl (4.0mm Diameter)	
Midline Cortical (MC) Drills		
70-MC-0445	Reform MC Drill, 2.7mm (for 4.5mm screw)	NavLock - Solera™ X.Xmm Tap Solid (any diameter, requires verification) 
70-MC-0450	Reform MC Drill, 3.2mm (for 5.0mm screw)	
70-MC-0455	Reform MC Drill, 3.7mm (for 5.5mm screw)	
70-MC-0465	Reform MC Drill, 4.7mm (for 6.5mm screw)	
Midline Cortical (MC) Drill Guide		
70-MC-0040	Reform MC Drill Guide	No Tool Card Non-Navigated Instrument
Probe		
70-RF-0003	Reform, Reform Ti, Reform MC Lenke Probe (Offset = 5.2mm Diameter)	NavLock - Thoracic or Pedicle Probe (requires verification) 

SURGICAL TECHNIQUE

2

TOOL CARD ASSIGNMENT (continued)

TABLE 3: Precision Spine Navigated Instrument and Medtronic StealthStation™ Tool Card Cross Reference

(Array color assignments may differ from those depicted below. Ensure the arrays are attached to the assigned instruments.)

Part Number	Description	Corresponding Required Tool Card
Taps		
70-RF-0545 to 70-RF-0595	Reform®, Reform Ti Taps <i>(for 4.5mm - 9.5mm screws, Non-Cannulated)</i>	NavLock™ - Solera™ X.Xmm Tap Solid <i>(diameter specific, requires verification)</i>
70-RH-1045 to 70-RH-1095	Reform HA Taps <i>(for 4.5mm - 9.5mm screws, Non-Cannulated)</i>	
70-MC-0545 to 70-MC-0595	Reform MC Midline Cortical Taps <i>(for 4.5mm - 9.5mm screws, Non-Cannulated)</i>	
70-3L-0545 to 70-3L-0595	SureLOK™ MIS 3L/Reform Ti Taps <i>(for 4.5mm - 9.5mm screws, Cannulated)</i>	
Polyaxial Drivers		
70-RF-0700	Reform Polyaxial Driver <i>Non-Cannulated</i>	NavLock - Solera 5.5/6.0 MAS Cannulated Driver <i>(requires verification)</i> <i>Tool Card Image Unavailable</i>
70-RT-0720	Reform Ti Polyaxial Driver <i>Non-Cannulated</i>	
70-RT-1720	Reform Ti Polyaxial Driver <i>Cannulated</i>	
70-MC-0700	Reform MC Midline Cortical Polyaxial Driver <i>Non-Cannulated</i>	
70-3L-0700	SureLOK MIS 3L Polyaxial Driver <i>Cannulated</i>	
70-RT-1750	Reform Ti MIS CT Polyaxial Driver <i>Cannulated</i>	
Modular Drivers		
70-RM-0800	Reform Modular Driver <i>Non-Cannulated</i>	NavLock - Solera 5.5/6.0 MAS Cannulated Driver <i>(requires verification)</i> <i>Tool Card Image Unavailable</i>
70-MC-0800	Reform Ti/MC Modular Driver <i>Non-Cannulated</i>	
70-MC-1800 70-MC-1820*	Reform Ti/MC Modular Driver <i>Cannulated</i>	

* SPECIAL ORDER: 70-MC-1820 Reform Ti/MC Modular Driver, Cannulated T25 RIGHT HAND THREADED

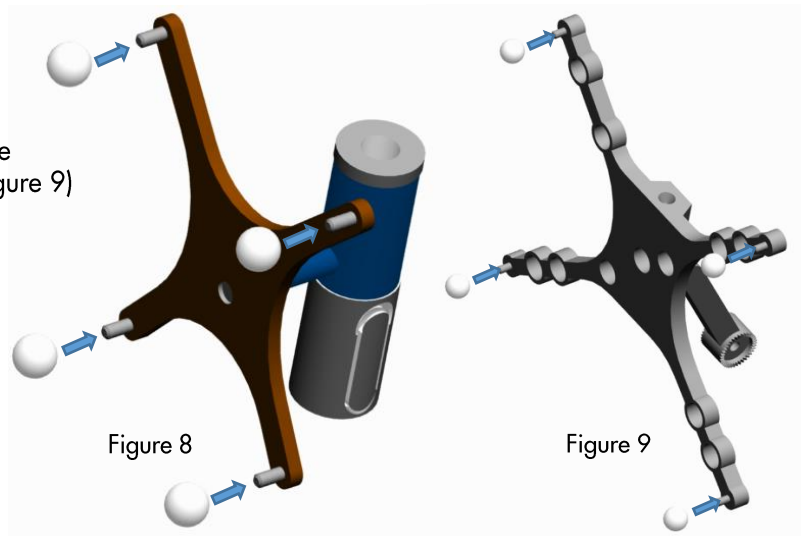
SURGICAL TECHNIQUE

3

INSTRUMENT ATTACHMENT

1. MARKER ASSEMBLY

Attach four (4) disposable reflective spheres each to the NavLock™ Tracker (Figure 8) and Reference Frame (Figure 9)



2. INSTRUMENT ATTACHMENT

Insert the appropriate Tracker onto the instrument shaft such that the Tracker latches securely engage the instrument's mating undercut geometry.

Refer to Figure 10 Tracker Attachment and Table 1 for Instrument Tool Card Assignment.

If a Tracker fails to properly lock onto an instrument (minimal up and down movement), correct the issue or DO NOT navigate the instrument.

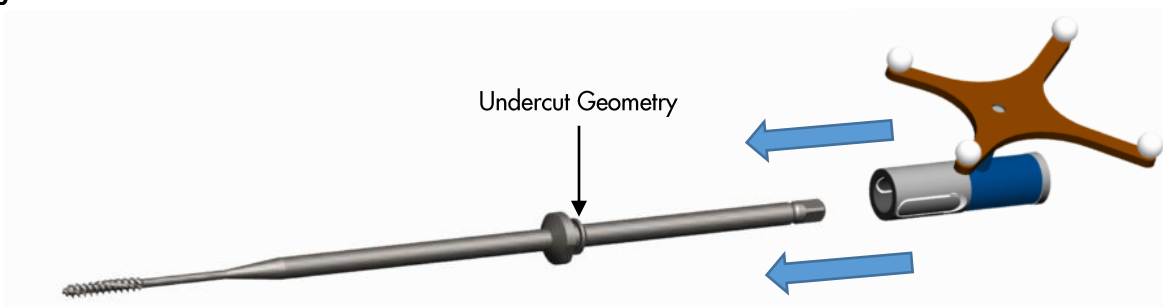


Figure 10

SURGICAL TECHNIQUE

3

INSTRUMENT VERIFICATION (General Guidelines)

1. INSTRUMENT VERIFICATION

- Hold the instrument as perpendicular to the reference frame as possible and insert the distal tip of each instrument/tracker assembly, one at a time, into the divot (Figure 11).
- Bottom the tip into the reference frame and hold in the aligned orientation until instrument verification is achieved.

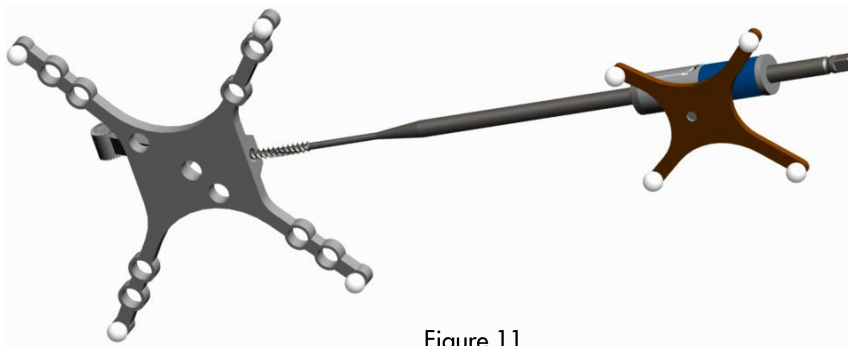


Figure 11

2. VERIFICATION CONFIRMATION

- Aim the camera in the direction of the reference frame.
- Use the Tracking View window to confirm that the reference frame and trackers are in range and can be tracked by the system (Figure 12).

BLUE Dots = successful tracking

GREEN Dots = reference frame

YELLOW Dots = blocked and/or malfunctioning spheres *(Not shown in Figure 12)*

BLUE Triangle = proximity of camera from the reference frame



Figure 12

SUCCESSFUL Verification

- Indicated on the instrument tool card on the “**VERIFY INSTRUMENTS**” screen.
- The card transitions from **BLUE** to **GREEN** once verified and an audible notification plays

UNSUCCESSFUL Verification

- Card remains **BLUE** and an audible notification plays
- Ensure sterile spheres are clean and both the instrument and reference frame are visible in the tracking view.
- Repeat steps until the instrument is successfully verified.
- If verification is not achieved, **DISCONTINUE** navigation.

SURGICAL TECHNIQUE

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NAVIGATE PROJECTION

Simulated instrument and implant tip locations and/or projected tip locations need to be compared to actual locations on bone landmarks prior to use.

Figure 13 shows options for navigating an instrument or navigating a projection.

NAVIGATE A PROJECTION

- Select the following:

SELECT PROJECTION → SHOW as CYLINDER

- Adjust the Width and Length with the + and – buttons and select the correct sizes or the closest larger sizes
- Select **NAVIGATE PROJECTION**

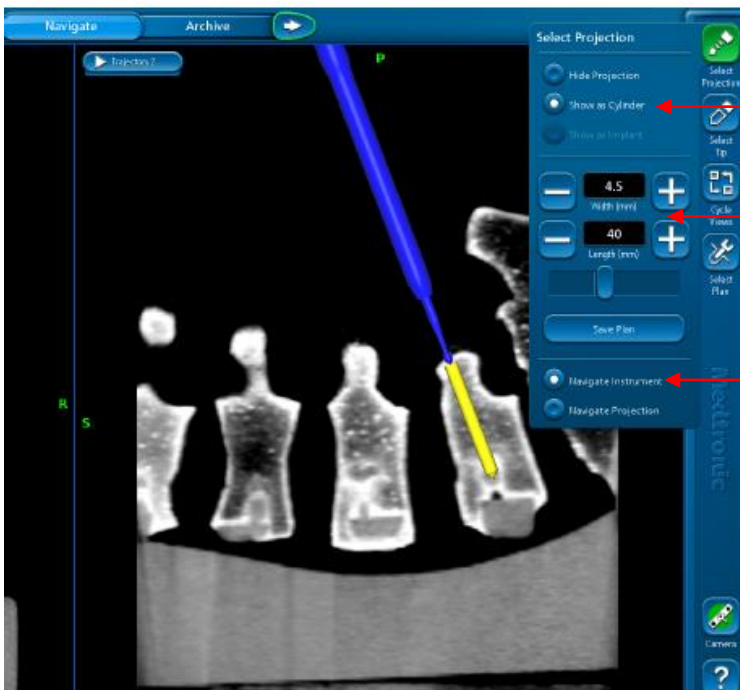


Figure 13

1. SELECT PROJECTION

2. SHOW as CYLINDER

3. WIDTH and LENGTH Adjustments

4. NAVIGATE PROJECTION

Notes:

- A positive projection is only used with screws added to a driver. Positive projections (shown as yellow in Figure 13) start at the instrument tip and extend away from the instrument.
- A negative projection is used with all other instruments. Negative projections start at the tip and extend up toward the instrument handle.

CAUTION: A positive projection that is shorter than the screw being used can result in adverse events since the actual screw will be deeper than what is depicted in the viewing screen.

Compare instrument location relative to known bony landmarks versus what is depicted on the screen prior to instrument use.

SURGICAL TECHNIQUE

5

INSTRUMENT-SPECIFIC VERIFICATION GUIDELINES

***In the event that the instrument width projection size cannot be obtained, use the next largest width size.**

AWLS & DRILLS

- Place the instrument's tip in the reference frame divot and verify the instrument
- Navigate a **NEGATIVE projection***

Part Number	Description	Diameter	Length
Awls			
70-RF-0001	Reform [®] , Reform Ti, Reform MC Awl	4.0mm	18.3mm
70-3L-0001	SureLOK [™] 3L, Reform Ti MIS CT Awl	4.0mm	15.8mm
Midline Cortical (MC) Drills			
70-MC-0445	Reform MC Drill (for 4.5mm screw)	2.7mm	58.2mm
70-MC-0450	Reform MC Drill (for 5.0mm screw)	3.2mm	58.2mm
70-MC-0455	Reform MC Drill (for 5.5mm screw)	3.7mm	73.4mm
70-MC-0465	Reform MC Drill (for 6.5mm screw)	4.7mm	73.4mm

TABLE 4: Precision Spine Navigated Awls and Drills Dimensions

LENKE PROBE

- Place the Tracker on any Navigated Precision Spine **5.5mm Tap**
 - Navigated Precision Spine 5.5mm Taps: 70-MC-0555, 70-RF-0555, 70-RH-00555, 70-3L-0555, or 70-MD-0555*
- Place the tap's tip in the reference frame divot and verify the tap
- Remove the tap and place the Lenke Probe, 70-RF-0003, on the Tracker
- Navigate a **NEGATIVE projection***

Part Number	Description	Diameter <i>(equals 2 times probe offset from centerline)</i>	Length
Lenke Probe			
70-RF-0003	Reform, Reform Ti, Reform MC Lenke Probe	5.2mm	50mm

TABLE 5: Precision Spine Navigated Probe Dimensions

TAPS

- Place the tap's tip in the reference frame divot and verify the instrument (Figure 14)
- The Precision Spine Tap size and corresponding Solera solid tap tool card size should be the same.

If the corresponding TAP TOOL CARD is NOT PRESENT

- Navigate a **NEGATIVE projection**
- Select the width corresponding to the tap outer diameter and a negative 40mm length projection to simulate tap geometry



Figure 14

SURGICAL TECHNIQUE

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SCREW DRIVER VERIFICATION GUIDELINES

*In the event that the instrument width projection size cannot be obtained, use the next largest width size.

**If the instrument positive projection length cannot be obtained, use the next shortest size. Use of the next shortest size will result in the projection appearing deeper by an amount equal to the difference between the actual length and projected length.

CAUTION: Confirm actual instrument location relative to boney landmarks prior to proceeding!

POLYAXIAL SCREW DRIVERS & POLYAXIAL SCREW ASSEMBLIES MODULAR SCREW DRIVERS & MODULAR BONE SCREWS

Simulator Verification

- Secure a Tracker on the Precision Spine Simulated 5.5/6.0 MAS Driver instrument, 70-SD-0700 (Figure 15).
- Place the simulator's tip in the reference frame divot (Figure 16) and obtain the verification reading of the **CD Horizon Solera 5.5/6.0 MAS Driver Tool card**.

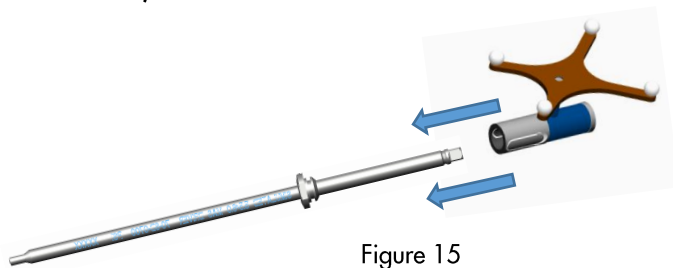


Figure 15

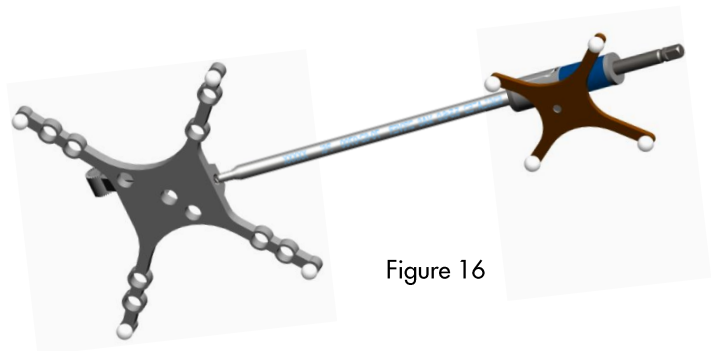


Figure 16

Screw Driver Attachment

- Remove the Tracker from the simulator instrument and attach it on the screw driver to be used (Figure 17).
- Secure the desired size polyaxial screw to the screw driver.

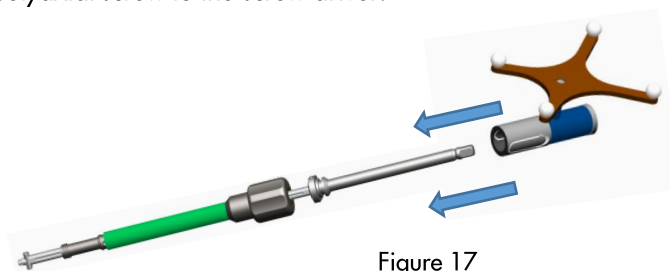


Figure 17

Screw Driver - Screw Confirmation

- Confirm proper mating Screw Driver - Screw combinations as well as corresponding Medtronic screw tool cards/Medtronic Screw part numbers utilizing Tables 7 through 14 in Section 8.
- Either navigate a **POSITIVE projection**** that matches the screw diameter* and length** to be implanted or select the corresponding Medtronic 5.5/6.0 MAS Tool Card cross referenced in Tables 7 thru 14 in Section 8.
- Alter the diameter and length to match each screw size being implanted.

Reconfirmation

- Reconfirm simulated and actual tip location agreement prior to use and after every change

SURGICAL TECHNIQUE

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ACQUIRING SCANS

- Install the reference frame on a rigid anatomical landmark per Medtronic instructions.
- After installing patient reference frame, obtain 3D CT images of the desired anatomical area.
- Transfer images to the StealthStation™

7

NAVIGATING INSTRUMENTS

- Perform surgery as indicated by the surgical technique for the corresponding implant system

Reform® Pedicle Screw System
Reform Ti Pedicle Screw System
Reform MC Midline Cortical Screw System
SureLOK™ MIS 3L Percutaneous Screw System
Reform Ti MIS CT Modular Percutaneous Screw System

Navigated Instrument Accessories

- Non-navigated midline cortical drill guide which aid in maintaining navigated drill position and orientation
- Simulated 5.5/6.0 MAS Driver to aid in driver registration

CAUTION: Instrument verification and accuracy checks need to be assessed prior to every use! Accuracy assessments can be accomplished by placing each navigated instrument at known anatomical landmarks and confirming that the instrument tip location and orientation is in agreement with the simulated depiction in the Navigation screen.

Reassessing system accuracy should be performed throughout the procedure including whenever any changes are made to the instrument being navigated, or the manner in which the instrument is depicted in the simulation (i.e. change in implant size or change in projection or change from navigate tip to navigate projection, etc.). Be cognizant of what is being navigated (the simulated instrument or the projection).

Care should be taken to limit bending forces on navigated instruments as instrument deflection can influence navigational accuracy. Do not use bent or otherwise damaged instrumentation. Patient repositioning, spinal manipulation, reference frame movement all can affect navigational accuracy.

Follow the manufacturer's (Medtronic) instructions for system setup, use, trouble shooting, and all warnings and precautions.

If the navigation system does not appear to be accurate despite troubleshooting (e.g., resetting the system), do not rely on the navigation system.

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

TABLE 6: Mating Screw and Tool Card Reference Chart

Reference Table	Catalog #	Description	Compatible Precision Spine Screws
Polyaxial Drivers			
Table 7	70-RF-0700	Reform® Polyaxial Driver NON-CANNULATED	<ul style="list-style-type: none"> • Preassembled Reform Polyaxial, Reduction, HA, Uniplanar, Uniplanar Reduction, and MIS Uniplanar Reduction Screws
Table 8	70-RT-0720	Reform Ti Polyaxial Driver NON-CANNULATED	<ul style="list-style-type: none"> • Preassembled Reform Ti Polyaxial, Reduction, and HA Screws • Reform Ti Modular Screws or Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Modular Tulips (39-MT-0301 or 39-MT-0302) or Reform Ti Modular Tulips (39-MT-0401 or 39-MT-0402)
Table 9	70-RT-1720	Reform Ti Polyaxial Driver CANNULATED	<ul style="list-style-type: none"> • Preassembled CANNULATED Reform Ti Polyaxial and Reduction Screws • CANNULATED Reform Ti MODULAR Screws or CANNULATED Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Modular Tulips (39-MT-0301 or 39-MT-0302) or Reform Ti Modular Tulips (39-MT-0401 or 39-MT-0402)
Table 10	70-MC-0700	Reform MC Midline Cortical Polyaxial Driver, NON-CANNULATED	<ul style="list-style-type: none"> • Reform MC Midline Cortical Modular Screws preassembled to Reform MC Midline Cortical Modular Tulips (59-MT-0301 or 59-MT-0302)
Table 11	70-3L-0700	SureLOK™ MIS 3L Polyaxial Driver CANNULATED	<ul style="list-style-type: none"> • SureLOK MIS 3L Polyaxial Screws
Table 12	70-RT-1750	Reform Ti MIS CT Polyaxial Driver CANNULATED	<ul style="list-style-type: none"> • Preassembled CANNULATED Reform Ti Reduction Screws • Reform Ti Modular Screws or Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Ti MIS CT Modular Extended Tab Tulip (64-MT-0403) Reform Ti Modular Reduction Tulips (39-MT-0402)
Modular Drivers			
Table 13	70-RM-0800	Reform Modular Driver NON-CANNULATED	<ul style="list-style-type: none"> • Reform Modular Screws
Table 14	70-MC-0800	Reform Ti/MC Modular Driver NON-CANNULATED	<ul style="list-style-type: none"> • Reform MC Midline Cortical Modular Screws or Reform Ti Modular Screws
Table 15	70-MC-1800 70-MC-1820*	Reform Ti/MC Modular Driver CANNULATED	<ul style="list-style-type: none"> • CANNULATED Reform MC Midline Cortical Modular Screws or CANNULATED Reform Ti Modular Screws

* SPECIAL ORDER: 70-MC-1820 Reform Ti/MC Modular Driver, Cannulated T25 LEFT HAND THREADED

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- PREASSEMBLED Reform:
 - Polyaxial Screws
 - Reduction Screws
 - HA Screws
 - Uniplanar Screws
 - Uniplanar Reduction Screws
 - MIS Uniplanar Reduction Screws

Table 7: Reform® Navigated POLYAXIAL Driver, Non-Cannulated, 70-RF-0700

XX = Screw Length

Screw Size (Ø x Length)	Mating Reform Screw Part Numbers			Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
	Polyaxial	Reduction	HA		
4.5mm x XXmm	39-PA-45XX	39-RP-45XX	39-PH-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.0mm x XXmm	39-PA-50XX	N/A	N/A	Solera 5.5/6.0MAS 5.0m x XXmm	558400050XX
5.5mm x XXmm	39-PA-55XX	39-RP-55XX	39-PH-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-PA-65XX	39-RP-65XX	39-PH-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-PA-75XX	39-RP-75XX	39-PH-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-PA-85XX	39-RP-85XX	39-PH-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-PA-8500	39-RP-8500	39-PH-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-PA-8511	39-RP-8511	39-PH-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-PA-95XX	39-RP-95XX	N/A	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-PA-9500	39-RP-9500	N/A	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-PA-9511	39-RP-9511	N/A	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	39-PA-10XX	39-RP-10XX	N/A	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	39-PA-1000	39-RP-1000	N/A	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	39-PA-1011	39-RP-1011	N/A	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511
Screw Size (Ø x Length)	Uniplanar	Uniplanar Reduction	MIS Uniplanar Reduction	Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
4.5mm x XXmm	39-UP-45XX	39-RU-45XX	39-MU-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.5mm x XXmm	39-UP-55XX	39-RU-55XX	39-MU-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-UP-65XX	39-RU-65XX	39-MU-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-UP-75XX	39-RU-75XX	39-MU-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- PREASSEMBLED Reform Ti:
 - Polyaxial Screws
 - Reduction Screws
 - HA Screws
- Reform Ti Modular Screws or Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Modular Tulips (39-MT-0301 or 39-MT-0302) or Reform Ti Modular Tulips (39-MT-0401 or 39-MT-0402)

Table 8: Reform® Ti Navigated POLYAXIAL Driver, Non-Cannulated, 70-RT-0720

XX = Screw Length

Screw Size (Ø x Length)	Mating Reform Ti Screw Part Numbers			Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	Polyaxial	Reduction	Modular		
4.5mm x XXmm	39-TP-45XX	39-TR-45XX	39-SB-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.5mm x XXmm	39-TP-55XX	39-TR-55XX	39-SB-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-TP-65XX	39-TR-65XX	39-SB-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-TP-75XX	39-TR-75XX	39-SB-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-TP-85XX	39-TR-85XX	39-SB-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-TP-8500	39-TR-8500	39-SB-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-TP-8511	39-TR-8511	39-SB-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-TP-95XX	39-TR-95XX	39-SB-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-TP-9500	39-TR-9500	39-SB-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-TP-9511	39-TR-9511	39-SB-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	39-TP-10XX	39-TR-10XX	39-SB-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	39-TP-1000	39-TR-1000	39-SB-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	39-TP-1011	39-TR-1011	39-SB-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511
Screw Size (Ø x Length)	Reform Ti HA	Reform MC Modular		Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
4.5mm x XXmm	39-HT-45XX	59-BP-45XX		Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.0mm x XXmm	N/A	59-BP-50XX		Solera 5.5/6.0MAS 5.0m x XXmm	558400050XX
5.5mm x XXmm	39-HT-55XX	59-BP-55XX		Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-HT-65XX	59-BP-65XX		Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-HT-75XX	59-BP-75XX		Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-HT-85XX	59-BP-85XX		Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-HT-8500	59-BP-8500		Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-HT-8511	59-BP-8511		Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-HT-95XX	59-BP-95XX		Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-HT-9500	59-BP-9500		Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-HT-9511	59-BP-9511		Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	N/A	59-BP-10XX		Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	N/A	59-BP-1000		Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	N/A	59-BP-1011		Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- PREASSEMBLED CANNULATED Reform Ti:
 - Polyaxial Screws
 - Reduction Screws
- CANNULATED Reform Ti Modular Screws or CANNULATED Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Modular Tulips (39-MT-0301 or 39-MT-0302) or Reform Ti Modular Tulips (39-MT-0401 or 39-MT-0402)

Table 9: Reform® Ti Navigated POLYAXIAL Driver, Cannulated, 70-RT-1720

XX = Screw Length

Screw Size (Ø x Length)	Mating CANNULATED Reform Ti Screw Part Numbers			Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	Polyaxial	Reduction	Modular		
5.5mm x XXmm	39-TC-55XX	39-TD-55XX	39-SK-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-TC-65XX	39-TD-65XX	39-SK-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-TC-75XX	39-TD-75XX	39-SK-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-TC-85XX	39-TD-85XX	39-SK-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-TC-8500	39-TD-8500	39-SK-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-TC-8511	39-TD-8511	39-SK-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-TC-95XX	39-TD-95XX	39-SK-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-TC-9500	39-TD-9500	39-SK-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-TC-9511	39-TD-9511	39-SK-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	39-TC-10XX	39-TD-10XX	39-SK-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	39-TC-1000	39-TD-1000	39-SK-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	39-TC-1011	39-TD-1011	39-SK-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511
Screw Size (Ø x Length)	CANNULATED Reform MC Modular Screws			Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
5.5mm x XXmm	59-BC-55XX			Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	59-BC-65XX			Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	59-BC-75XX			Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	59-BC-85XX			Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	59-BC-8500			Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	59-BC-8511			Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	59-BC-95XX			Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	59-BC-9500			Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	59-BC-9511			Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	59-BC-10XX			Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	59-BC-1000			Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	59-BC-1011			Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform MC Midline Cortical Modular Tulips (59-MT-0301 or 59-MT-0302)

Table 10: Reform® MC Midline Cortical Navigated POLYAXIAL Driver, Non-Cannulated, 70-MC-0700

XX = Screw Length

Screw Size (Ø x Length)	Mating Reform MC Midline Cortical Screw Part Numbers	Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
4.5mm x XXmm	59-BP-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.0mm x XXmm	59-BP-50XX	Solera 5.5/6.0MAS 5.0m x XXmm	558400050XX
5.5mm x XXmm	59-BP-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	59-BP-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	59-BP-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	59-BP-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	59-BP-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	59-BP-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	59-BP-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	59-BP-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	59-BP-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	59-BP-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	59-BP-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	59-BP-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

SURGICAL TECHNIQUE

COMPATIBLE PRECISION SPINE SCREWS

- SureLOK MIS 3L Polyaxial Screws

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MATING SCREW and TOOL CARD CROSS-REFERENCE

Table 11: SureLOK™ MIS 3L Navigated POLYAXIAL Driver, 70-3L-0700

XX = Screw Length

Screw Size (Ø x Length)	Mating SureLOK MIS 3L Screw Part Numbers	Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
5.5mm x XXmm	63-CP-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	63-CP-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	63-CP-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	63-CP-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	63-CP-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- PREASSEMBLED CANNULATED Reform Ti:
 - Reduction Screws
- Reform Ti Modular Screws or Reform MC Midline Cortical Modular Screws PREASSEMBLED to Reform Ti MIS CT Modular Extended Tab Tulip (64-MT-0403) or Reform Ti Modular Reduction Tulip (39-MT-0402)

Table 12: Reform® Ti MIS CT Navigated POLYAXIAL Driver, Cannulated, 70-RT-1750

XX = Screw Length

Screw Size (∅ x Length)	Mating CANNULATED Reform Ti Screw Part Numbers		Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	Reduction	Modular		
5.5mm x XXmm	39-TD-55XX	39-SK-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-TD-65XX	39-SK-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-TD-75XX	39-SK-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-TD-85XX	39-SK-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-TD-8500	39-SK-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-TD-8511	39-SK-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-TD-95XX	39-SK-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-TD-9500	39-SK-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-TD-9511	39-SK-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	39-TD-10XX	39-SK-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	39-TD-1000	39-SK-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	39-TD-1011	39-SK-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511
Screw Size (∅ x Length)	CANNULATED Reform MC Modular Screws		Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
5.5mm x XXmm	59-BC-55XX		Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	59-BC-65XX		Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	59-BC-75XX		Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	59-BC-85XX		Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	59-BC-8500		Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	59-BC-8511		Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	59-BC-95XX		Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	59-BC-9500		Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	59-BC-9511		Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	59-BC-10XX		Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	59-BC-1000		Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	59-BC-1011		Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

- Reform Modular Screws

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MATING SCREW and TOOL CARD CROSS-REFERENCE

Table 13: Reform® Navigated MODULAR Driver, Non-Cannulated, 70-RM-0800

XX = Screw Length

Screw Size (∅ x Length)	Mating Reform Modular Screw Part Numbers	Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
4.5mm x XXmm	39-MS-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.5mm x XXmm	39-MS-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	39-MS-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	39-MS-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	39-MS-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	39-MS-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	39-MS-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	39-MS-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	39-MS-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	39-MS-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	39-MS-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	39-MS-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	39-MS-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- Reform MC Midline Cortical Modular Screws
- Reform Ti Modular Screws

Table 14: Reform® Ti/MC Navigated MODULAR Driver, Non-Cannulated, 70-MC-0800

XX = Screw Length

Screw Size (Ø x Length)	Mating Modular Screw Part Numbers		Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	Reform MC	Reform Ti		
4.5mm x XXmm	59-BP-45XX	39-SB-45XX	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.0mm x XXmm	59-BP-50XX	N/A	Solera 5.5/6.0MAS 5.0m x XXmm	558400050XX
5.5mm x XXmm	59-BP-55XX	39-SB-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	59-BP-65XX	39-SB-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	59-BP-75XX	39-SB-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	59-BP-85XX	39-SB-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	59-BP-8500	39-SB-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	59-BP-8511	39-SB-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	59-BP-95XX	39-SB-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	59-BP-9500	39-SB-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	59-BP-9511	39-SB-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	59-BP-10XX	39-SB-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	59-BP-1000	39-SB-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	59-BP-1011	39-SB-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

SURGICAL TECHNIQUE

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MATING SCREW and TOOL CARD CROSS-REFERENCE

COMPATIBLE PRECISION SPINE SCREWS

- CANNULATED Reform MC Midline Cortical Modular Screws
- CANNULATED Reform Ti Modular Screws

Table 15: Reform® Ti/MC Navigated MODULAR Driver, Cannulated, 70-MC-1800, 70-MC-1820*

XX = Screw Length

Screw Size (Ø x Length)	Mating Modular Screw Part Numbers		Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	CANNULATED Reform MC	CANNULATED Reform Ti		
4.5mm x XXmm	59-BC-45XX	N/A	Solera 5.5/6.0MAS 4.5m x XXmm	558400045XX
5.0mm x XXmm	59-BC-50XX	N/A	Solera 5.5/6.0MAS 5.0m x XXmm	558400050XX
5.5mm x XXmm	59-BC-55XX	39-SK-55XX	Solera 5.5/6.0MAS 5.5m x XXmm	558400055XX
6.5mm x XXmm	59-BC-65XX	39-SK-65XX	Solera 5.5/6.0MAS 6.5m x XXmm	558400065XX
7.5mm x XXmm	59-BC-75XX	39-SK-75XX	Solera 5.5/6.0MAS 7.5m x XXmm	558400075XX
8.5mm x XXmm	59-BC-85XX	39-SK-85XX	Solera 5.5/6.0MAS 8.5m x XXmm	558400085XX
8.5mm x 100mm	59-BC-8500	39-SK-8500	Solera 5.5/6.0MAS 8.5m x 100mm	55840008500
8.5mm x 110mm	59-BC-8511	39-SK-8511	Solera 5.5/6.0MAS 8.5m x 110mm	55840008511
9.5mm x XXmm	59-BC-95XX	39-SK-95XX	Solera 5.5/6.0MAS 9.5m x XXmm	558400095XX
9.5mm x 100mm	59-BC-9500	39-SK-9500	Solera 5.5/6.0MAS 9.5m x 100mm	55840009500
9.5mm x 110mm	59-BC-9511	39-SK-9511	Solera 5.5/6.0MAS 9.5m x 110mm	55840009511
10.5mm x XXmm	59-BC-10XX	39-SK-10XX	Solera 5.5/6.0MAS 10.5m x XXmm	558400015XX
10.5mm x 100mm	59-BC-1000	39-SK-1000	Solera 5.5/6.0MAS 10.5m x 100mm	55840001500
10.5mm x 110mm	59-BC-1011	39-SK-1011	Solera 5.5/6.0MAS 10.5m x 110mm	55840001511

* SPECIAL ORDER: 70-MC-1820 Reform Ti/MC Modular Driver, Cannulated T25 RIGHT HAND THREADED

INDICATIONS

PRECAUTIONS

The **Navigated Instrument** System instruments should only be used by surgeons who are fully experienced in the use of such instruments and the specialized navigated spinal surgery techniques.

CONTRAINDICATIONS

The **Navigated Instrument** System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device
11. Contraindications under the Reform® Spinal Fixation System, Reform® HA Coated Spinal Fixation System, SureLOK™ SLC Extended Tab Screw System, Medtronic Navigation StealthStation™ System are all applicable to the use of the Navigated Instrument System.

POTENTIAL ADVERSE EFFECTS

All possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any, or all, of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase in spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS

The following are warnings for this device.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only. **AN IMPLANT SHOULD NEVER BE RE-USED.** Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. Titanium components should not be used with stainless steel components within the same system.
14. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
15. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
16. Precision Spine does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
17. The use of the Navigated Instrument System should only be used with the indicated pedicle screw systems.
18. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
19. Users must ensure that surgical accuracy be assessed before the procedure and repeatedly throughout the procedure by positioning the tip of each navigated instrument on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. When verifying the accuracy of the Navigated Drivers, the accuracy test must include the Screw (of which diameter and length are selected/entered in the software) assembled securely onto the driver. The screw tip will be placed on an identifiable anatomical landmark and compared to the tip location as displayed on the screen.
20. In the event of a registration failure or suspected inaccuracy, the Navigated Instruments should not be used with the Navigation System and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.



Precision Spine, Inc.

2050 Executive Drive, Pearl, MS 39208

Customer Service: 1.888.241.4773

Phone: 601.420.4244

Toll Free: 877.780.4370

Fax: 601.420.5501

www.precisionspineinc.com

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