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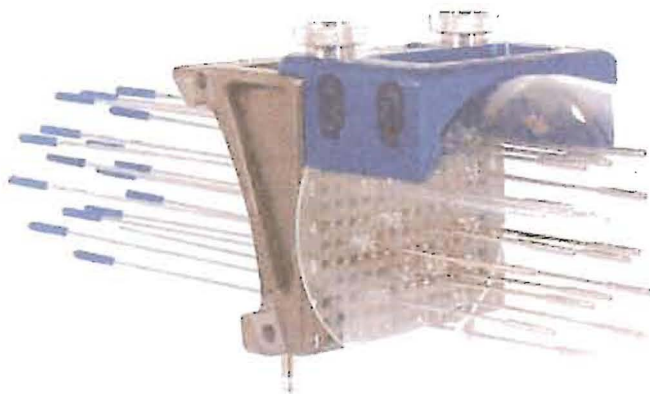
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INSTRUCTIONS FOR USE

HDR Prostate Contour TP Template For Rigid Metal Needles!

Catalog # 1106



Illustrated above is the HDR Contour Template for Rigid Needles configured for B&K with inserted 17 Gauge Rigid Metal Needles and Protective Cone installed.

Available Accessories through this Company:
Spare Locking Needle Collets (Pack of 12), Protective Cone & Mick Leg Rest.



Form #: 405-105 Rev B: 04/15/11



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HDR Prostate Contour TP Template

Catalog # 1106

For Rigid Metal Needles ONLY!

WHEN ORDERING THE HDR CONTOUR TP TEMPLATE, IT IS IMPERATIVE TO SPECIFY THE NEEDLE GAUGE TO BE USED AND THE MODEL OF THE ULTRASOUND TO ASCERTAIN COMPATIBILITY. THE TEMPLATES ARE AVAILABLE FOR MOST OF TODAY'S EXISTING ULTRASOUND STEPPING DEVICES AND FOR A VARIETY OF RIGID METAL NEEDLES.

PARTS LIST

TEMPLATE INCLUDES:

1.	1 ea.	HDR Contour Template Body	Cat. # 1106-02
2.	30 ea.	Locking Collets	Cat. # 1105-01
3.	1 ea.	Collet Wrench	Cat. # 1105-02
4.	2 ea.	Protective Cone Lock Knobs	Cat. # 0404-12
5.	2 ea.	Mounting Pins	Cat. # 9807-08
6.	1 ea.	Instructions for Use Manual	Form. # 405-105

OPTIONAL ACCESSORIES (Can be ordered separately)

1.	1 ea	Pack of Locking Needle Collets (12 / pack) - <u>17 Gauge</u>	Cat. # 1105-01-17
		1 ea Pack of Locking Needle Collets (12 / pack) - <u>18 Gauge</u>	Cat. # 1105-01-18
		1 ea. Pack of Locking Needle Collets (12 / pack) - <u>1.65mm</u>	Cat. # 1105-01-1.65
2.		Protective Cone	Cat. # 9807-PC
3.		Leg Rest	Cat. # 9807-LS

Catalog # 1106

HDR Prostate Contour TP Template
Matrix: A – G / 1 – 7
13 Rows and 13 Columns
Hole Spacing; 5.0 mm
Total of 169 Holes
Shown: B&K Compatible



Labeling

All Templates are laser engraved with letters to denote horizontal rows of Needle Channels and with numbers to denote the vertical columns of Needle Channels. The numbering / lettering layout corresponds to the type of stepper being used. The Catalog number, needle gauge size and type are clearly inscribed on the top bar of the template for easy identification and traceability. The Serial Number is engraved on the underside of the top bar of the Template for traceability.

HDR Prostate Contour TP Templates For Rigid Metal Needles

Catalog # 1106

I. DESCRIPTION

The HDR Prostate Contour TP Template is designed as a needle guidance system used for Brach therapy treatment of the prostate. The Template is square in shape and contains an array of labeled needle channels to facilitate accurate placement of Rigid Metal Needles into the prostate. The needle channels are pre-drilled to accommodate threaded Locking Needle Collets and correspond to the needle channel layout of the type of Stepper being used. Tightening of individual Needle Collets ensure each Rigid Metal Needle is held firmly in place. The Needle Collets offer excellent needle-holding power while enabling unobstructed passage of the HDR source through the implanted needles. The Needle Collets prevent deformation of the Rigid Metal Needles while secured in locked position.

The HDR Prostate Contour TP Template is made of Aluminum and hard-coated. Two Titanium Protective Cone Lock Knobs are provided in order to facilitate docking the Protective Cone (provided separately) to the Template. Templates are fabricated for various gauge Rigid Metal Needles.

IMPORTANT NOTE:

The HDR Prostate Contour TP Template (Cat. # 1106) is designed for use with Rigid Metal Needles ONLY!

If the use of FlexiGuide Needles is desired, a different model template is required!

The HDR Prostate Contour TP Template was designed for use with transrectal ultrasound (TRUS) imaging guidance. This is accomplished by mounting the Template on a TRUS stepper / stabilizer system. The HDR Prostate Contour TP Template is provided with two vertically mounted pins located at the base for compatibility with the B&K platform or others.

II. FEATURES

The following features are notable for the HDR Prostate Contour TP Template for Rigid Metal Needles:

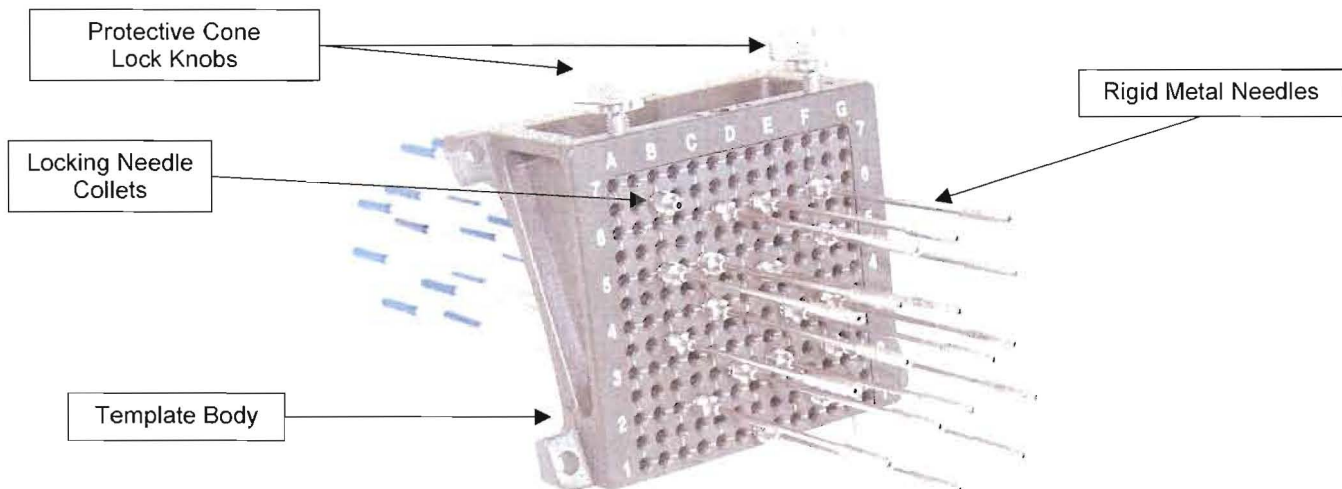
- Contoured to fit the sloping perineum.
- Individual Titanium Needle Collets ensure unsurpassed locking power on Rigid Metal Needles in the Template.
- Reusable and Autoclaveable.
- Provided with four suture holes allowing the Template to be directly sutured to the perineum.
- Resistance-free Bore Holes for smooth needle passage and guidance.
- It is used in conjunction with Ultrasound for enhanced needle guidance.
- Compatible with B & K, Siemens, Aloka and other Ultrasound Stabilizing Devices.
- Durable construction.

III. MATERIALS

The following materials are used in the HDR Prostate Contour TP Template:

- HDR Contour Template and Locking Plate Aluminum (Hard-coated)
- Lock Knobs and Locking Needle Collets Titanium

HDR Prostate Contour TP Template with inserted 17 Gauge Rigid Metal Needles.



IV. INDICATIONS FOR USE

The HDR Prostate Contour TP Template is indicated for high-dose rate irradiation of the prostate.

V. CONTRAINDICATIONS

As per acceptable clinical practice.

VI. CAUTIONS / PRECAUTIONS

1. Each physician is responsible for using the appropriate technique and determining the indication for use of the HDR Prostate Contour TP Template, based on his own experience, training and medical judgment.
2. The HDR Prostate Contour TP Template should only be used with the appropriate and matching Rigid Metal Needles. The Template is labeled according to Needle Size ordered.

USING NEEDLES OF SIZES OTHER THAN THOSE MATCHING THE TEMPLATE CAN LEAD TO SERIOUS MALFUCTIONS AND MISADMINISTRATIONS.

3. All components of the HDR Prostate Contour TP Template must be properly cleaned and sterilized prior to every use. See Page 9 for Cleaning and Sterilization protocols.
4. Prior to use, verify that the Rigid Metal Needles being used are of the correct size to match the Template's gauge size.
5. Prior to use, the physical condition of all HDR Prostate Contour TP Template components should be free of corrosion and in optimal working condition. Check for the integrity of the device after use. If corrosion or damage has occurred, the component has reached the end of its useful life and must be replaced.



VII. COMPLICATIONS

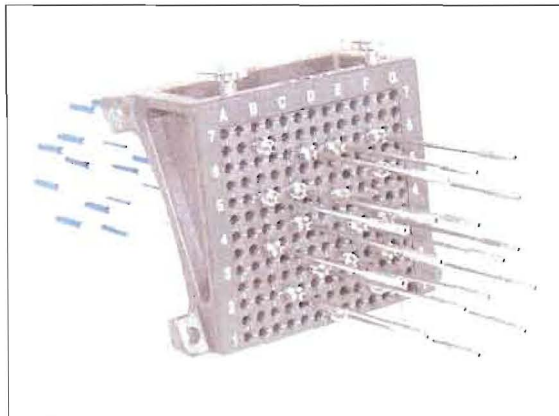
Possible complications associated with the HDR Prostate Contour TP Template are related to insertion and usage techniques of the Rigid Metal Needles and may result in perforation, bleeding, mucosal irritation and infection.

VIII. RECOMMENDED INSTRUCTIONS FOR USE

NOTE:

This Instruction for Use Manual reflects the use of the HDR Prostate Contour TP Template (# 1106), with **RIGID NEEDLES ONLY**. FlexiGuide Needles **CANNOT** be used in this HDR Prostate Contour Template. If the use of FlexiGuide Needles are desired, a different type of HDR Prostate Contour Template is required. Contact www.seedos.com for the appropriate HDR Prostate Contour Template.

HDR Contour Template (Catalog # 1106)



The HDR Contour TP Template shown with inserted empty Needle Collets and some with inserted Rigid Metal Needles in the Collets.



A close-up shows the Needle Collets threaded into the Needle Channels of the Template; some with inserted Rigid Metal Needles and some without.

Collet Wrench (Cat. # 1105-02)

Shown on right is the Collet Wrench. It is approx. 6" long and slitted throughout for unobstructed access to collets.

The Collet Wrench is made of St. Steel and serves to secure the inserted Rigid Metal Needles within the Template with ample guarantee of non-slippage.



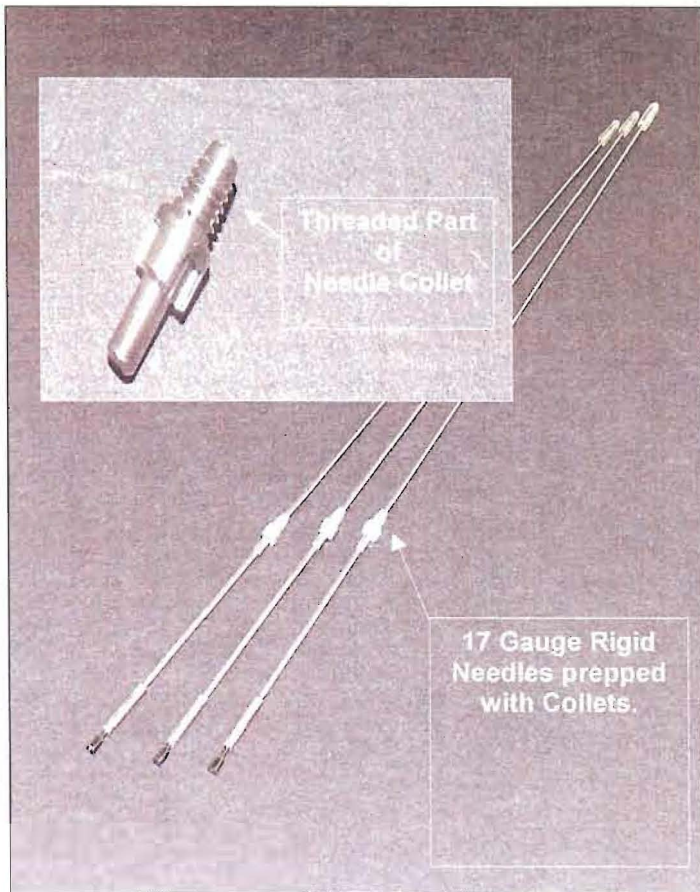
Needle Collet (Cat. # 1105-01)

Shown on left is the Collet Wrench with an inserted Locking Needle Collet. Collets are held captive within the Collet wrench when held horizontally.

Collets are made of Titanium.



RECOMMENDED INSTRUCTIONS FOR USE -



Inserting / Tightening the Rigid Metal Needle:

The following is the recommended process for inserting and tightening the Rigid Metal Needle in the Template:

- Remove the protective plastic cap from the needle tip.
- Slide the Locking Needle Collet onto the Rigid Metal Needle with the thread facing towards the Template. (See Photo at left).
- Insert the Rigid Metal Needle through the Template and into the prostate.
- Once in place, manually slide the Locking Needle Collet forward as far as possible against the Template.
- Slide the Collet Wrench over the protruding shaft of the Needle and attach it to the Locking Needle Collet. (With pressure against the Locking Collet, twist the Collet Wrench until it seats itself in the Locking Collet)
- Thread the Locking Needle Collet into the Template; only 4 turns are needed to fully insert the Needle Collet.
- To fully secure the implanted Rigid Metal Needle, turn the Collet Wrench clockwise 1/2 turn. To unlock the Needle, turn the Collet Wrench counter clockwise 1/2 turn.

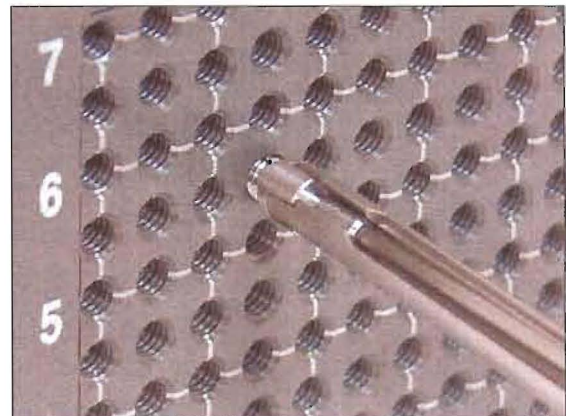
HDR Template with inserted Collet



The view above shows an inserted Rigid Metal Needle in the Template and the Collet Wrench attached to the Needle Collet.

The handle of the Collet Wrench is provided with a straight knurl. The Collet Wrench is slitted throughout to allow for the Collet Wrench to be dropped over the implanted Needle to facilitate access to individual Collets within a crowded array of implanted Needles.

Close-up of Needle Collet and Collet Wrench



The view above shows a close-up of the Needle Collet threaded into the Template.

The Collet Wrench has 3 protruding prongs which matches 3 grooves in the Needle Collet.

HOLD THE NEEDLE WRENCH HORIZONTALLY AND THE GROOVE FACING UPWARDS FOR THE NEEDLE COLLET TO HOLD WITHIN THE NEEDLE WRENCH.

RECOMMENDATION — PREVENTIVE MEASURES

Protect the protruding rigid needles by means of the Protective Cone (# 9807-PC).



The following is strongly recommended:

- Upon completion of the treatment, occlude the opening of the needle with either a needle cap or needle plug to prevent entry of foreign matter.
- Loosen the two Lock Knobs located on top of the template.
- Bundle the needles together and slide the Protective Cone over the implanted Needles.
- Dock the Protective Cone with the Template by turning the two Lock Knobs clockwise until the Cone is secured in place.
- Reverse the procedure at the start of a new treatment.

HDR TREATMENT

CAUTION:

Prior to the delivery of an HDR treatment, visually verify needle positions again to ascertain that all Rigid Metal Needles are still in their original positions as planned. ADJUST AS NEEDED.

1. Remove the Protective Cone from the Template by turning the Protective Cone Lock Knobs counterclockwise.
2. Carefully connect all HDR Source Guide / Transfer Tubes to all implanted needles.
3. Treat per plan.

CAUTION:

The process of connecting the Source Guide Tubes to the needles is delicate and utmost care and caution must be exercised during the coupling procedure of the remote afterloader to the needles.

POST HDR TREATMENT

1. Carefully disconnect all HDR Source Guide / Transfer Tubes from all implanted needles.
2. Hold onto the implanted needle with one hand while disconnecting the Source Guide / Transfer Tube with the other.
3. As needles are disconnected from Source Guide / Transfer Tubes, insert either needle caps or needle plugs over the open end of the needle to prevent foreign contaminants from entering the lumen of the needle.

IX. RECOMMENDED CLEANING PROCEDURE:

1. Upon completion of treatment, disassemble all components from the Template Body.
2. Soak all components in disinfectants as recommended by the hospital.
3. Immediately and thoroughly rinse all components with warm water.

Caution:

Prolonged exposure to some cleaning and disinfecting agents may affect the color of the Aluminum based structure and surface coating.

Caution:

Do not use Ultrasonic Cleaners or abrasive detergents.

X. STERILIZATION PROCEDURE

After disassembling components from the HDR Prostate Contour TP Template and a proper cleaning, insert all components in the autoclave for steam sterilization.

NOTE: This Sterilization procedure is valid for only the Mick HDR Prostate Contour TP Template and components. This does not include the Rigid Metal Needles, which are provided separately.

All parts contained in the set can be AUTOCLAVED via Gravity Displacement method by using either Sterilization Parameter below.

Temperature:	121°C or (250°F)	Temperature	132°C or (270°F)
Pressure	15 psig	Pressure	15 psig
Sterilization Time	30 Minutes	Sterilization Time	3 minutes

Warning:

The cleaning and sterilization processes above will provide a sterile product. Any deviation from these reprocessing instructions must be properly qualified before patient use.