The **CAPELLA™** Ultrasound System is Designed to Help the Clinician:

**identify** THE VESSEL OF INTEREST

**visualize** THE SURROUNDING ANATOMY
Use the Capella™ Ultrasound System in combination with the Capella™ Coaxial Micro-Introducer Kit to help access the vessel quickly.

**Patented Ultrasound Needle Guidance Helps:**
- Optimize the probability of needle placement in the vessel upon first pass compared to landmark/palpation technique
- Minimize the risk of complications

**The Capella™ Ultrasound System Helps the Clinician:**
- Identify vessels
- Visualize surrounding anatomy
- Assess vessel depth
- Visually compare catheter size relative to vessel
- Assess vasculature prior to access

21 Gauge Access Needle with Echogenic Tip

Assortment of .018" Guidewires for Varied Anatomies

Vessel Access With Up To a .038" Guidewire or Catheter

Easily Visualized Echogenic Needle Tip and Radiopaque Sheath and Dilator
MINIMALLY INVASIVE

micro-access

Easily Visualized Echogenic Needle Tip and Radiopaque Sheath and Dilator
Ordering Information

**CP1100** Capella™ Ultrasound System

Includes:
- Capella™ Ultrasound System
- A/C Adapter / Battery Charger
- Pole Clamp
- Tripod
- Probe Holder
- IFU
- Software
- 1 Year Warranty
- System Case

**CP1101** Capella™ Ultrasound System Starter Kit

Includes:
- Everything in the Capella™ Ultrasound System
  
  AND
- Reference Guide
- Probe Sheath Kits with Gel

**CP1104** Capella™ Ultrasound System Case

**CP1105** Capella™ Ultrasound System Power Supply

**CP1106** Capella™ Ultrasound System A/C Line Cord

**CP1107** Capella™ Ultrasound System Tripod

**CP1108** Capella™ Ultrasound System Probe Holder

**CP1109** Capella™ Ultrasound System Clamp Mount

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**CAPELLA™**

Coaxial Micro-Introducer Kit

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Sheath Size</th>
<th>Wire</th>
</tr>
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<tbody>
<tr>
<td>MK4181</td>
<td>4F</td>
<td>Stainless steel with stainless steel tip</td>
</tr>
<tr>
<td>MK4182</td>
<td>4F</td>
<td>Stainless steel with gold/tungsten tip</td>
</tr>
<tr>
<td>MK4183</td>
<td>4F</td>
<td>Nitinol with gold/tungsten tip</td>
</tr>
<tr>
<td>MK5181</td>
<td>5F</td>
<td>Stainless steel with stainless steel tip</td>
</tr>
<tr>
<td>MK5182</td>
<td>5F</td>
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</tr>
<tr>
<td>MK5183</td>
<td>5F</td>
<td>Nitinol with gold/tungsten tip</td>
</tr>
</tbody>
</table>

**Guidewire Diameter**
- 0.018"  

**Guidewire Length**
- 45 cm  

**Needle Gauge/Length**
- 21G / 7 cm  

**Unit of Measure**
- 10 / case
**CAPELLA Ultrasound System**

**Indications for Use**

The CAPELLA Ultrasound System is intended to provide ultrasound imaging of the human body. Specific clinical applications include:

- Adult Cephalic
- Neonatal Cephalic
- Pediatric
- Peripheral Vessel

**Warnings**

**Warning:** This product should only be operated by qualified medical personnel.

**Warning:** Only qualified personnel should remove outer housing from the CAPELLA Ultrasound System device. Hazardous voltages exist at several points within the system.

**Warning:** Do not operate the CAPELLA Ultrasound System or the CAPELLA Ultrasound System A/C Adapter in the presence of flammable anesthetics or gases. Explosion may result.

**Warning:** Do not use for ophthalmic indications. Ophthalmic use may cause patient injury.

**Warning:** Misuse of the CAPELLA Ultrasound System may result in damage to the equipment or personal injury.

**Warning:** Use only the CAPELLA Ultrasound System A/C Adapter to charge the CAPELLA Ultrasound System. Use of any other device to charge the CAPELLA Ultrasound System may damage the battery, may cause intermittent or unserviceable operation, may damage the system, may result in injury and will void warranty.

**Warning:** If a probe is damaged in any way, discontinue use immediately. Damage to the system may occur.

**Warning:** Avoid subjecting the system to excessive mechanical shock. Damage to the system may occur.

**Warning:** Do not allow liquid to enter the system, A/C adapter or connectors. Damage to the system may occur.

**Warning:** Do not attempt to sterilize the CAPELLA Ultrasound System. Damage to the system may occur.

**Warning:** Only qualified personnel should attempt to service this system. The CAPELLA Ultrasound System contains static sensitive components and circuits. Failure to observe proper static control procedures may result in damage to the system.

**Warning:** Opening or servicing the system or the probe housing by anyone other than Bard authorized service personnel.

**Warning:** Opening or servicing the A/C Adapter by anyone other than Bard authorized service personnel.

**Warning:** The CAPELLA Ultrasound System is not intended for fetal use.

**Warning:** Do not use the probe with high frequency surgical equipment. Doing so may damage the device.

**Warning:** The Guidewire should not be withdrawn through the needle. Damage or shearing of the sheath may occur.

**Warning:** If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit.

**Cautions:**

- Do not allow ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or isopropyl alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry couplant from the acoustic window (or face) of the probe.

- Do not subject the system to excessive vibration. Vibration may dislodge sensitive components and cause intermittent or unserviceable operation.

- Prior to each use, inspect the integrity of all power cords and connectors as well as the integrity of the unit itself. If any problems are found, discontinue use immediately and contact an authorized service representative. Use of a damaged power cord could damage the machine.

- During use, the A/C wall plug needs to be easily accessible. In case of emergency remove the power cord as soon as possible.

- Get in a comfortable position to avoid unnecessary strain when using the device.

- Attach the power source in such a way as to prevent damage. Improper installation may damage power cords.

- Inspect the probe prior to each use. If damage to the cable or transducer face is noted, do not use the probe. Damage to the system may occur.

- Use only Bard cleaning and disinfection procedures and recommended disinfectants. Failure to do so may damage the device.

**Coaxial Micro-Introducer Kit**

**Indications for Use:**

The introducer sheath/dilator is indicated for percutaneous introduction of up to a 0.038 in. guidewire or catheter into the vascular system through an initial puncture of 0.027 in. or 0.035 in. guidewires. The introducer sheath/dilator is intended for use as an introducer to the CAPELLA Ultrasound System. Use of any other device to charge the CAPELLA Ultrasound System may result in damage to the system.

**Contraindications:**

None known.

**Warnings:**

- Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterilization or storage date has passed.

- The device has been designed for single patient use only. Reusing this medical device bears the risk of cross patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological materials can promote the contamination of the device with pyrogens and microorganisms, which may lead to infectious complications.

- Do not re-sterilize. After sterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or re-sterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

- After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

- Do not bend or distort the probe cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure, intermittent or unpredictable operation.

- Do not subject the system to excessive mechanical shock. Damage to the system may occur.

- Avoid patient contact with the console. The console may get warm when it is on for an extended period of time. This may cause patient injury.

**Precautions:**

- The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If, however, a certain threshold has been passed, biological effects may occur. While the CAPELLA Ultrasound System acoustic output parameters fall well below the FDA thresholds for adverse biological effects, any given ultrasound procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- Do not exceed the voltage or current capacity of the system in any liquid including disinfectants. Doing so may damage the system.

- Only apply commercially available ultrasonic couplant, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe.

- Use water or isopropyl alcohol and a soft cloth to remove couplant from the acoustic window (or face) of the probe. Failure to do so may scratch the acoustic window.

Please consult package insert for more detailed safety information and instructions for use.

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