Hip X-Ray Alignment Guide Instructions
Description
Accurate planning of hip replacement surgery is essential to assure that the correct implants are available and to help plan the reproduction of limb length and offset. The X-Guide™ aligns the pelvis and projects a radio-opaque ruler at the level of the hip joint and is recorded on the x-ray medium.

The device consists of an acrylic structure that assists the x-ray technician while taking a preoperative planning pelvis x-ray for hip surgery. The X-Guide™ consists of an alignment tower, an adjustable grid, and “cross hairs” to align the pelvis and accurately place a ruler projection at the level of the hip joint. The X-Guide™ is Patent Pending.

Indications
The X-Guide™ is designed to help obtain an x-ray for planning a hip surgery. The X-Guide™ assists the technician in two ways. The X-Guide™ aligns the pelvis for a supine anterior-posterior standard planning x-ray. The X-Guide™ also projects a ruler at the level of the hip that is recorded on the x-ray medium (film or digitizing media).

Contraindications
Use the X-Guide™ for pre-operative planning x-rays only. The X-Guide™ should not be used for diagnostic hip or pelvis x-rays as the device projections on the x-ray may obscure pathology.

The X-Guide™ relies on accurate placement of the device and accurate measurement of the patient. The X-Guide™ is calibrated only for the standard x-ray source to recording medium distances (source-to-image-receptor distance, or SID) of 40” and 48”. Abnormal pelvis anatomy such a previous fracture or developmental abnormalities may result in the projected ruler being inaccurate.

The X-Guide™ is manufactured from acrylic plastic and barium epoxy inlays. Do not use in patients allergic to these materials.

Precautions
Use of the X-Guide™ requires a working knowledge of the anatomy of the pelvis, especially the bony landmarks. Therefore, this devise should only be used by someone trained and experienced with pelvis anatomy. This device should not be placed on abnormal skin lesions and should be cleaned with antibacterials after every use.

Disclaimer
SunMedica is not responsible for injury as a result of misuse or abuse of this product. Call SunMedica for any questions regarding proper use at 1-800-995-8715.
DIRECTIONS FOR USE

Patient Position
The patient is placed supine on the x-ray table. The legs are positioned to assure a neutral alignment of the proximal femur to the acetabular socket. This is commonly achieved by placing the knee caps facing directly anterior. This may be difficult to achieve in the markedly arthritic hip joint. It may be necessary to slightly flex the hip(s) to align the X-Guide™ tower and achieve a true A-P pelvis x-ray. The position of the lower extremities needed should be recorded and the information conveyed to the orthopedic surgeon requesting the planning x-ray.

Define The Boney Landmarks
The X-Guide™ rests on the skin above boney landmarks. The three boney landmarks are: the symphysis pubis (SP) and the two anterior superior iliac spines (ASIS). See Figure 1. Usually, even in the obese patient, these areas are readily palpable on the supine patient. If needed, the patient can assist by retracting the panniculus and better exposing the boney prominences.

Measurement Of Pelvis Thickness
The grid on the X-Guide™ needs to be adjusted for the patient pelvis thickness and for the type of standard x-ray (40” or 48” SID). The tower on the X-Guide™ has two scales. There is a a scale for the 40” SID and another scale for the 48” SID. The marks on the tower are the thickness of the patient measured in inches. See Figure 2.

With the patient supine on the x-ray table and the pelvis flat (both table to ASIS distances equal) use a caliper to measure the distance in inches from the x-ray table to the ASIS. See Figure 3. Adjust the grid platform on the calibrated tower portion of the X-Guide™ to this number. Again, be aware that the adjustment is different for the standard 40” and 48” SID’s. The top of the grid platform aligns with the appropriate mark on the tower. Figure 4 shows the correct placement for a 48” SID and a patient thickness of 8”.

If the technician isn’t sure if the patient’s pelvis is flat on the x-ray table, then measure both right and left ASIS to table distances and average them. Again adjust the grid to the appropriate mark on the tower.

Placement Of X-Guide™ On Patient
The patient is supine on the x-ray table and preliminarily lined up over a large cassette or image receptor (recording medium).
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The X-Guide™ has three “feet” that are placed over the three boney prominences. Within each foot is a series of x-ray markers. Adjust the X-Guide™ such that the equal sized markers align over the boney prominences. For example, for an average patient, the medium sized radio graphic markers in the feet of the X-Guide™ line up with the two ASIS’s and the symphysis pubis. The X-Guide™ will fit most pelvises. The large marks will line up over the boney prominences of large patients and the small marks will line up over the boney prominence of small patients. See Figure 5.

The x-ray markers in the feet will appear on the x-ray recording medium. This will assist the technician in improving their skills of placement of the X-Guide™. When reviewing the feet markers on the x-rays, it is necessary to keep in mind that parallax will result in the marks being superior and lateral for the ASIS marks and inferior for the SP mark. Also note that the ASIS is not a lateral projection of the ileac crest, it is inferior and medial to the flare of the crest. See Figure 6.

Patient Participation
The patient is generally able to hold the X-Guide™ and assist in the alignment of the x-ray. Once the X-Guide™ is in the correct position over the ASISs and SP, have the patient grip the lateral uprights of the ASIS portion of the X-Guide™. See Figure 7. Practice with the patient to make sure that they understand how to hold the X-Guide™ firmly against the boney landmarks.

Alignment Of The X-Guide™ & X-Ray Equipment
Using the alignment light from the x-ray tube, move the patient’s pelvis until the two crosses on the X-Guide™ line up in line with the alignment light. See Figure 8. It is important that the feet of the X-Guide™ continue to be firmly pressed against the SP and the ASISs.

The patient can see the X-Guide™ crosses and the x-ray tube alignment light. With minimal instructions, the patient can effectively hold the X-Guide™ and align the crosses with the x-ray tube alignment light. See Figure 9.

If the patient cannot hold this position while the x-ray is taken, then use foam wedges/blocks to assist the patient. As noted above, in very arthritic patients, it may be necessary to partially flex the hips to put the pelvis in the anatomic position under the x-ray tube. Another potential problem is a stiff arthritic spine such as in ankylosing spondylitis. This may require a slight sitting position to achieve the anatomic position of the pelvis.

Figure 5

Figure 6

Figure 7

Figure 8
Taking The X-Ray
Use standard exposure settings for an AP pelvis x-ray. The ruler grid is a mixture of barium and epoxy. The ruler projection will be apparent under normal exposure setting. See Figure 10. The technician can use each x-ray to improve their skill at using the X-Guide™. The learning curve should be short for a skilled technician.

Checking The Accuracy The X-Ray
The easiest method to check the accuracy is to evaluate an X-Guide™ x-ray on a patient with a previous hip replacement. Determine the size of the components used on the previous surgery. Use the ruler magnification transparency to determine the magnification of the x-ray at the hip joint. Using the same magnification ruler, check the projected ruler. See Figure 10. The accuracy should be within 2 to 4%. If there are problems call or email SunMedica for assistance.

USING TEMPLATES TO PLAN SURGERY
Digitized X-Rays
Most Picture Archive Communication Systems (PACS) have a magnification correction option. Use the projected ruler to “click” on a known distance. Use the ends of the ruler to improve the accuracy of the correction (for an example, 6 cm). Once the image is corrected, then the template software should be more accurate.

Another option is to display the x-ray on a large monitor. Adjust the magnification until the projected ruler measures one centimeter between grid lines. This will adjust the image to zero magnification, meaning life sized. Now use zero magnification templates (so called 100% templates).

If zero magnification templates are not available, then adjust the image magnification on the computer screen until the projected rule matches the magnification of the templates available, for example, 18% (so called 118% templates). See Figure 11.

Film Based Images
Place the x-ray film on a good view box. Using the magnification ruler transparency, determine the magnification of the projected grid. Use templates with this grid magnification. For example; for a grid magnification of 18% (commonly referred to as 118% magnification) use templates of that magnification (so called 118% templates). Unfortunately, the user of the X-Guide™ will soon discover that the common templates are not always accurate at the level of the hip. An alternative is to have the plain x-ray digitized and us the above method for digital images.
CLEANING INSTRUCTIONS
The feet of the X-Guide™ contact the patient’s skin and the patient grips the X-Guide™ as part of the process, therefore the X-Guide™ surfaces need to be cleaned after each use. As soon as the x-ray is taken, clean the contact surfaces with an appropriate antibacterial/antiviral solution using the instructions for the use of that particular product.

ORDERING INFORMATION
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