Has anyone really thought about the requirements for drilling living human bone tissue – until now?

C~Bit™

## *Analysing the Needs*

For decades, orthopaedic surgery has been supplied with drill bits derived from industrial-style manufacturing technology. The requirements for wood, metal, plastic and bone are very different, since bone is living tissue and must be treated accordingly. Accuracy, thermal damage, sharpness, sterility, strength, control and cost are just some of the issues associated with drilling living bone tissue.

The orthopaedic drill bit is fundamental to most orthopaedic procedures, yet designs fall short of a solution which provides surgeons with the ultimate in drill bit design technology. Accurate drilling of a hole is not limited to surgeon control, and exact securing of implants is most important if maximum implant life is to be realised. Specific design instrumentation plays an important role. The right equipment will enable hospitals, nurses and surgeons to achieve the best surgical outcomes.

When analysing drilling needs, it is important to consider the requirements for drilling holes in living bone tissue, the changing environment of orthopaedic surgery, and the availability of new technologies.

Most orthopaedic drill bit designs meet just a few of these requirements, but there is a need to satisfy them all – including an additional feature such as a soft tissue-friendly flute profile. With orthopaedic drill bits, it is preferable for hospitals to rely on one simple solution which suits the needs of all orthopaedic systems. There is now an orthopaedic drill bit designed to suit all orthopaedic systems, which addresses all the needs of orthopaedic surgery today. Inexpensive, accurate, sharp and sterile, first time, every time – no exceptions.

**Introducing C-Bit™**

Orthopaedic surgeons don't just rely on accuracy and cutting efficiency to drill a hole. Drill bits with both bending and torsion strength are a great advantage, but imagine a drill bit that has incredible drilling control, while minimising over-drilling, reducing soft tissue, surgical glove and drill guide damage.

## *Your solution*

Cingular Orthopaedics has developed a drill bit system that will suit 99% of orthopaedic systems in the market today. The system has been designed to ensure an inexpensive, accurate, sharp and sterile instrument is provided to the surgeon and patient – every time.

Cingular Orthopaedics provides you with a product that meets high surgical standard requirements, and eliminates the inherent risks of other multiuse drill bits. You can count on Cingular's C-BitTM, since they are not worn, damaged or broken, and pose no cross-contamination risks to your patient.

## *Sterilising and Packaging*

As resistant strains of bacteria and viruses become increasingly widespread, the issue of sterility becomes more of a risk. Once exposed to human tissue, multiuse orthopaedic drill bits have the potential to cross contaminate. Infections as a result of surgery are extremely difficult to treat and are also very costly to our health system. Orthopaedic surgery has become exceptionally refined in some areas of infection control, but has been overlooked in others – such as in the use of drill bits.

The C-BitTM process uses the highest packaging standards, which eliminates potential impurities. This packaging is efficient but without compromise. Inside are stickers for traceability and re-ordering. C-BitTM is supplied in boxes of 5, 10, 20, 50 and 100 units.

## *Design*

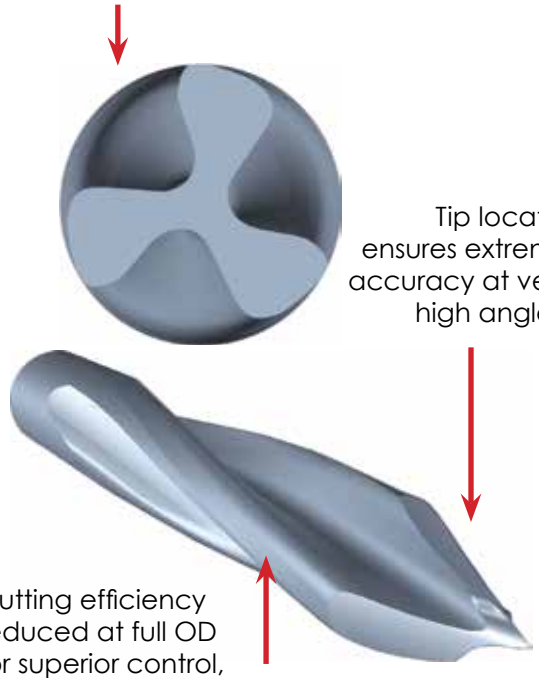
C-Bit™ has been designed with careful consideration to the requirements of orthopaedic surgery. C-Bit™ will outperform any other orthopaedic drill bit on the market today. It provides surgeons with certainty, peace of mind and confidence that it will be sterile, and will cut through bone tissue accurately, with ease and total control, while minimising damage caused to soft tissue.

The design features include a controlled cutting cam-like edge that delivers maximum cutting efficiency where needed, and ultimate control during the drilling process. The flute geometry has been designed to reduce drill guide, surgical glove, soft tissue damage and prevent over-drilling holes. C-Bit™ is the result of many years of optimisation. It has been engineered to provide superior performance and strength, as well as minimal bending during a drilling procedure to ensure correct hole alignment.

It is without question that surgeons will prefer a product that performs the best. C-Bit™ is an extremely safe, predictable, high performance surgical instrument for all conditions. Using computer modelling, C-Bit™ has the ultimate performance – both in cutting efficiency and strength.

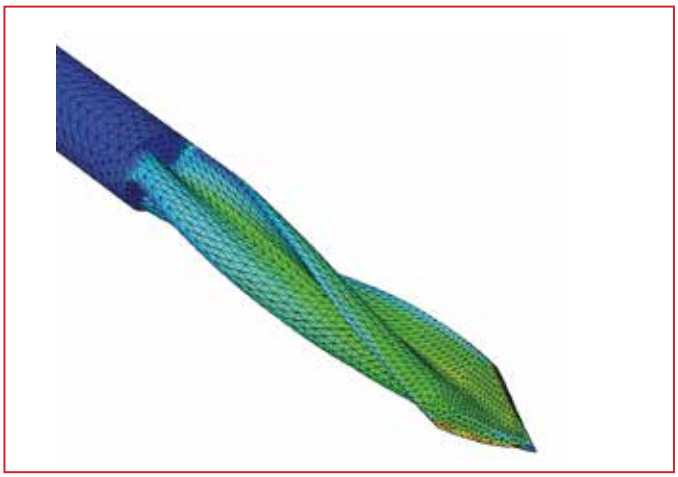
The unique design of C-Bit™ achieves a reduced manufacturing cycle time, which means cost savings to your facility. C-Bit™ is, without a doubt, the most advanced orthopaedic drill bit on the market today.

Radius leading flute edge relief minimises over drilling, reduces soft tissue, surgical glove and drill guide damage - and improves user control.



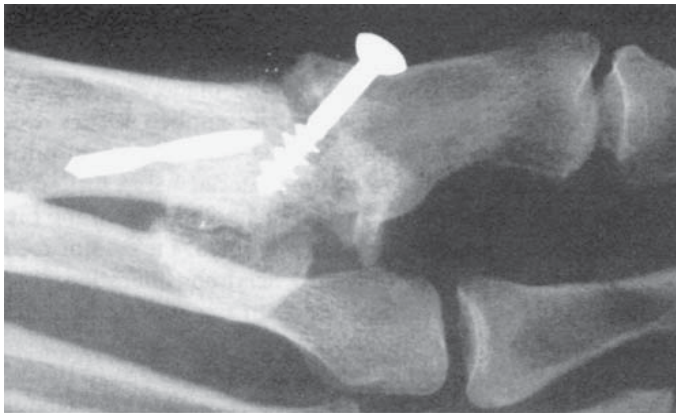

## *Computer Modelling*

The C-Bit™ design process has used finite-element analysis, to determine the stresses applied to a drill bit during a drilling procedure. Drill bits are prone to breakage, which can cause surgical complications. The analysis has been a key factor in the design process, producing a drill bit with incredible torsion and bending properties. C-Bit™ is an exceptionally strong drill bit, which reduces the possibility of drill bit breakage even in the most challenging conditions.



Multiuse drill bits were once the obvious choice. Today, there is a far superior alternative.

C-Bit™ surpasses a high performance instrument upgrade. It is the complete innovative solution that eliminates potential drill bit cross-contamination issues, at an affordable price.



**Broken drill bit**

No more dull, damaged, broken or contaminated drill bits. C-Bit™ is more than just a new high performance drill bit. It addresses issues which other drill bits do not.

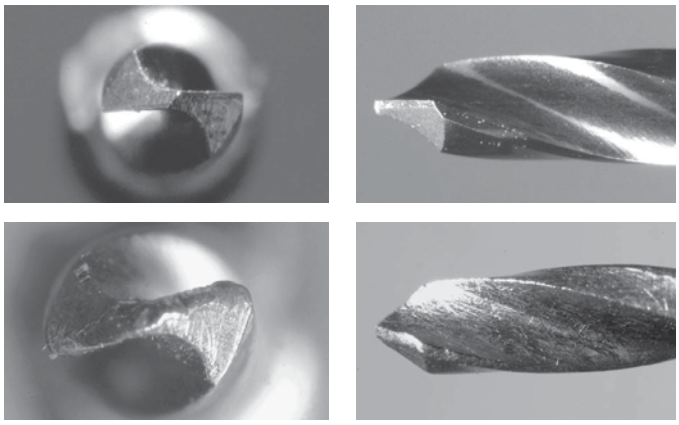
## *Why disposable?*

Historically, instruments that were once multiuse have become disposable, not only because of the potential risks they could cause but simply because it is more economical to supply them this way. There is, without question, re-processing costs involved with the decontamination, cleaning and sterilising of instruments after use.

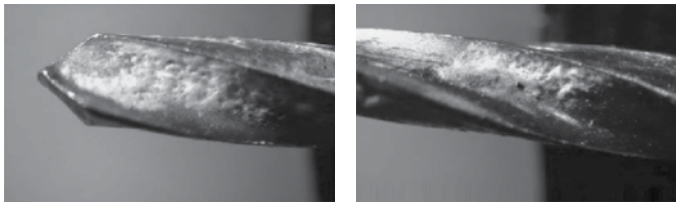
A drill bit that does not perform during a procedure adds to potential implant failure. The cost involved with revision surgery is far greater when compared to the cost of a single-use C-Bit™. The technology is now available to produce and supply an orthopaedic drill bit where the overall cost benefit far outweighs the potential risks that blunt, damaged or contaminated drill bits cause.

C-Bit™ is a unique and revolutionary single-use drill bit that delivers superior drilling performance and guaranteed sterility, at an affordable disposable price – first time, every time. No exceptions.

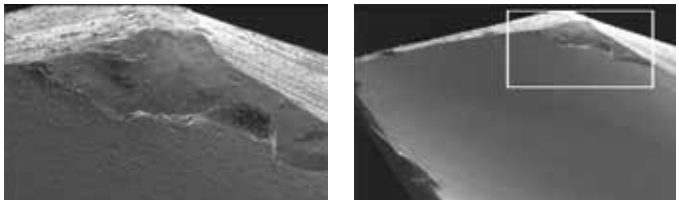
## *Drill bits have no quality assurance after first use*



## *Decontamination is ineffective*



## *Brittle metal failure is a real risk*



## *The C~BitTM approach*

Continuing to approach the surgical drill bit market with a multiuse product strategy is not in line with striving for better surgical results – for the medical professional and certainly not for the patient.

**With C-Bit™, we've put exceptional drilling technology firmly in an orthopaedic surgeon's hands.**

C-Bit™ is in line with other single-use medical technologies, such as the syringe, scalpel and saw blade. C-Bit™ design considerations provide surgeons and hospitals with a superior product that is cost effective, has improved clinical and tactical advantages, and helps reduce cross-contamination and infection rates.

Now there is a better alternative to re-using drill bits in surgery. C-Bit™ meets all associated issues with drilling living human tissue – first time, every time. No exceptions.

# If your patient had a choice between a new or used drill bit, which do you think they would choose?

# Medical standards require that syringes, needles, scalpels and saw blades are not re-used. So why do we continue to re-use drill bits?

| | **Problems frequently associated with traditional cutting tool designs and multiuse drill bits** | **C-Bit™ addresses issues associated with traditional type drill bit technology and the risks of multiuse drill bits** |
|---|---|---|
| **Cutting efficiency** | Multiple uses lead to dull cutting edges and poor drill bit performance. Drill bits used more than once are common in theatres across the world today. Dulling leads to frictional heat generation that can cause thermal damage to the patient, and coagulation of human tissue that blocks the drill bit flutes. | C-Bit™ guarantees a sharp drill bit first time, every time – no exceptions. C-Bit™, as the name suggests, is a single-use drill bit. The cutting edge is always at its optimum, which reduces heat generated from dull cutting surfaces. This reduces the risk of thermal damage to the patient and also decreases the rate of human matter coagulating in the drill bit flutes. |
| **Soft tissue damage** | When a hole is being drilled, the flutes of drill bits pose a hazard to surrounding soft tissue. The surrounding soft tissue tends to get caught in the flutes, causing soft tissue damage and further medical complications to the patient. | C-Bit™ has soft tissue-friendly flute geometry. Its geometry minimises the risk of tissue being hooked or caught in the flute. C-Bit™ has this design feature which is specific to the requirement for drilling living bone tissue. |
| **Cleaning and decontamination** | Human material coagulates very quickly on surgical instruments. This human tissue has strong adhesion, especially to the fluted surfaces of drill bits. If all human matter, including proteins, is not removed, autoclaving causes material to be 'baked' on to a drill bit. This is extremely difficult to remove. | Exposure of the C-Bit™ to human material is limited to one patient and, after use, the device is disposed of. This makes C-Bit™ 100% safe compared to its multiuse rivals, and completely eliminates the requirement for decontamination. |
| **Cross contamination and infection** | Bacteria and viruses are becoming more resistant to sterilising processes and some protein-based diseases cannot be destroyed by an autoclave. The risk of cross-contamination is increasing, and even more so in instruments such as drill bits. | C-Bit™ is gamma irradiated, and guaranteed to be sterile every time. The time has come for drill bits to pose no potential for cross-contamination to patients. Single-use means C-Bit™ will not be used on multiple patients, therefore eliminating cross-contamination and infections. |
| **Sterility** | Multiuse drill bits are subject to re-processing costs which are difficult to quantify. In addition, sterility cannot be guaranteed due to the difficulties with decontamination. | C-Bit™ is designed, inexpensively manufactured and sterile-packed for single use only, which means hospitals achieve valuable savings. These saving can be used for other critical purchases. |
| **Instrument fatigue and wear** | Multiuse drill bits are subject to wear and metal fatigue that can lead to drill bit breakage. In addition, most drill bit designs lack bending or torsional strength, which can also lead to drill bit breakage. Most three-fluted drill bits rely on high carbon stainless steel for edge rigidity and structural strength. However, this material is prone to destructive failure. | C-Bit™ is new – every time – so the risk of metal wear or fatigue is eliminated. The cross-sectional design is also indestructible during normal service. Laboratory testing demonstrates that it will only deform in adverse conditions, and will not break. This makes C-Bit™ much safer than its competitors, because there is little or no chance of fragments being left behind in the patient's body. |
| **Breakthrough control** | Traditional drill bit designs have little or no tactile response on breakthrough. The drilling operator has almost no warning to decrease axial load to prevent the drill bit from plunging into tissues beyond the far cortex. Uncontrollable breakthrough may lead to soft tissue damage and complications to the patient. | The C-Bit™ has a built in cam-like feature on its cutting face which gradually reduces axial resistance and effectively alerts the drilling operator when the drill bit is about to breakthrough the far cortex. This provides the operator with sufficient time to decrease axil load prior to breakthrough. This minimizes the drill bit plunging and thus decreases soft tissue damage. |
| **Instrument damage** | Multiuse drill bits are prone to damage during procedures, cleaning and re-processing. | C-Bit™ is designed for single use, eliminating damage caused from re-use and re-processing. |
| **Quality assurance** | Drill bits have no quality assurance after their first use. Drill bits are cutting tools and perform optimally when sharp and new. Dull, re-used drill bits can cause thermal damage to the patient, which may lead to implant failure. | C-Bit™ is a precision cutting instrument. Like all drill bits, it is best used when sharp, so it is supplied for single use, decreasing thermal damage and improving screw purchase, leading to better fixation and overall improved surgical outcomes. |
| **Multiuse versus single use** | Multiuse poses multiple risks. | C-Bit™ does away with all the risks associated with its multiuse rivals. The greatest risk is not using a C-Bit™ |
| **Accuracy, slippage, and skiving** | Slippage, skiving and poor control are major design factors influencing the outcomes of clinical procedures in operating theatres. Until now, drill bit designs have evolved very little in orthopaedic surgery. They are manufactured from technology developed decades ago, which is arguably outdated. | C-Bit™ has been designed to be 'all-terrain', accurate up accurate up to 65 degrees off the perpendicular, without slippage or skiving. The tip is designed to accurately locate the drill bit with one touch, giving surgeons the utmost confidence of accurate drill bit placement. |
| **Drill Guide Damage** | Drill bits which have a sharp cutting edge at full diameter pose potential damage to the sleeve of a drill guide. The sharp edges of the drill bit can cause burring of the drill guide. The effect of this is not limited to the drill bit jamming or catching inside the drill guide. Once the drill guide is damaged the drill bit will continue to cause further damage to the drill guide resulting in damage to the drill bit and the potential of burrs entering the body. | The C-Bit™ design leading edge has no potential to damage the drill guide. The radius leading edge spins smoothly in the drill guide with no risk of engaging. This completely eliminates the potential of the drill bit jamming or drill guide becoming damaged from the drilling procedure. Additionally, this means that there is no risk of burrs being left in the patient. |
| **Surgical Glove Damage** | Traditional sharp fluted drill bits can cause damage to surgical gloves and poses potential cross contamination to the surgeon and patient. | C-Bit™ radius leading edge is surgical glove friendly and minimises the potential for surgical gloves to become torn or damaged during a drilling procedure. |
| **Cost** | Drill bits can vary in quality and cost, depending on the metal stock, manufacturing time and technique, and secondary processes such as straightening. Overall metal choice and design effects production output per hour, which drives up a higher end-cost. | Our manufacturing technique and revolutionary design means C-Bit™ is an uncompromisingly superior drill bit, both in quality and design. C-Bit™ has the perfect synergy of incredible performance at low cost prices. Why pay more for outdated technology? |

| | Two Fluted | Competitor 1 | Competitor 2 | C-Bit™ |
|---|---|---|---|---|
| Cutting Efficiency | ✓ | ✓ | ✓ | ✓ |
| Accuracy | X | ✓ | ✓ | ✓ |
| Low Heat | ✓ | ✓ | ✓ | ✓ |
| Bending Moment | X | ✓ | ✓ | ✓ |
| Polar Moment | X | X | ✓ | ✓ |
| Sharp Everytime | ? | ? | ? | ✓ |
| Sterile | ? | ? | ? | ✓ |
| Breakthrough | X | X | X | ✓ |
| Soft Tissue Friendly | X | X | X | ✓ |
| Drill Guide Friendly | X | X | X | ✓ |
| Surgical Glove Damage | X | X | X | ✓ |
| Cost | X | X | X | ✓ |

C-Bit™ scores 12 out of 12 – a better product at a less expensive price. But is it really true? Ask your product specialist for a trial and decide for yourself. C-Bit™ is the only drill bit that addresses all the issues associated with drilling living human bone tissue.

**C~Bit™** *Anything else is just a drill bit.*

One simple solution

One easy decision

Inexpensive, accurate, sharp, sterile.
First time, every time – no exceptions.

C~Bit™

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