CRANIAL TECHNOLOGIES NEW PATIENT INFORMATION FORM

Patient Information

Child's legal name: _____ Gender: ☐ Male ☐ Female

Preferred name: _____ DOB: _____

Information for Parent/Guardian 1

Name: _____

Relationship to patient: _____ DOB: _____

Address: _____ City: _____ State: _____ ZIP code: _____

Home number: _____ Cell number: _____ Work number: _____

E-mail address: _____ Employer: _____

Information for Parent/Guardian 2

Name: _____

Relationship to patient: _____ DOB: _____ ☐ Use address listed above

Address: _____ City: _____ State: _____ ZIP code: _____

Home number: _____ Cell number: _____ Work number: _____

E-mail address: _____ Employer: _____

Primary Insurance Information

Name of insurance company: _____ Policyholder's name: _____

Group number: _____ Policy number: _____ Phone number: _____

Is the patient covered by Medicaid or AHCCCS? ☐ Yes ☐ No

Secondary Insurance Information

Name of insurance company: _____ Policyholder's name: _____

Group number: _____ Policy number: _____ Phone number: _____

Your Child's Medical Care

Pediatrician: _____ Phone number: _____

Address: _____ City: _____ State: _____ ZIP code: _____

Physical therapist: _____ Phone number: _____

Address: _____ City: _____ State: _____ ZIP code: _____

Specialist: _____ Phone number: _____

Address: _____ City: _____ State: _____ ZIP code: _____

Which of these medical providers referred your child to Cranial Technologies?

☐ Pediatrician ☐ Physical Therapist ☐ Specialist ☐ Other: _____

Primary Communication

To help our office share information with you as easily as possible, please select a primary contact for the following purposes:

☐ I give Cranial Technologies permission to email me (patient paperwork, exit photos, patient survey, education and information on products and services) using the email address listed for (select one): ☐ Parent/Guardian 1 ☐ Parent/Guardian 2

☐ I give Cranial Technologies Tech permission to contact me via phone to leave messages (scheduling changes, insurance communication, weather-related closures, etc.) using the phone number listed for (select all that apply): ☐ Parent/Guardian 1: ☐ Home ☐ Cell ☐ Work ☐ Parent/Guardian 2: ☐ Home ☐ Cell ☐ Work

Assignment & Release

I hearby assign my insurance benefits to be paid directly to Cranial Technologies. I understand that I am financially responsible for any non-covered services, collection agency fees and or attorney fees. I also authorize the provider to release any information required to process this claim.

Parent/Guardian signature: _____ Date: _____

Printed Name: _____

DOC Band® Informed Consent

INSTRUCTIONS
This is an informed consent document that has been prepared by Cranial Technologies, Inc. to inform you of the risks involved with the use of the DOC Band® for cranial remolding.

INTRODUCTION
The DOC Band is a proprietary thermoplastic construct device of a semi-rigid outer shell thermo-bonded to a foam inner lining. It was developed in 1988 as a conservative treatment for an asymmetrical head shape, of a non-synostotic origin, which is defined as positional plagiocephaly. The DOC Band is dynamic and does not rely on passive growth alone. It is most effective when used in the first 12 months of life, when brain growth is rapid. However, we have found that the DOC Band corrects positional deformation of the skull up to 18 months of age.

ALTERNATIVE TREATMENT
Non-treatment is an alternative; however, the consequences of untreated plagiocephaly are unclear at this time. Repositioning the infant off the flattened occiput may be advised in mild cases, but becomes ineffective once the infant is able to reposition themselves (typically after 3 to 4 months of age). Surgery may be considered for older infants, but is typically reserved for only the most severe cases, and only after all other forms of conservative intervention have been exhausted.

RISKS INVOLVED WITH CRANIAL REMODELING USING THE DOC BAND
There are some risks involved with the use of the DOC Band for cranial remodeling. However, the success of treatment and avoidance of complications is directly related to strict compliance with instructions given at the time of fitting.

- **Dynamic Pressure:** Because the DOC Band applies dynamic pressure directed to constrain growth at the prominent areas on the skull and encourages growth in flattened areas, regular growth adjustments must be made to accommodate brain growth. Due to the closed environment of the DOC Band, noncompliance to regular visits may result in skin breakdown, and asymmetrical and/or vertical growth of the skull.

- **Skin Breakdown:** If written instructions provided by Cranial Technologies are strictly adhered to, proper skin health can be maintained. However, noncompliance may result in skin irritation, pressure areas, open sores and/or infection.

- **Perspiration/Heat Rash:** It is common for the child to experience increased perspiration during the first three days of wear while adjusting to the DOC Band. In some cases, a child may develop a heat rash where perspiration tends to collect.

- **Care of the DOC Band:** Proper cleaning and handling of the DOC Band is clearly explained in a written handout provided at the time of fitting. However, compliance is crucial to avoid problems.

    1. Any solution applied to the inner liner, other than Isopropyl Alcohol, may result in skin irritation, skin burns, skin breakdown and/or infection.
    2. Failure to maintain cleanliness of the child's head and the DOC Band, as instructed, may result in bacterial buildup, skin breakdown and/or infection.

- **Wearing the DOC Band**: Strict compliance to wearing the band 23 hours a day, as directed, has been shown to produce significant correction of positional plagiocephaly. Correction differs with each child and results may vary. Noncompliance may result in undesired results, stunted or nonexistent correction, and growth at holding points causing skin breakdown and/or destruction of the dynamic forces built into the band.

The DOC Band cost includes the DSi®, Dsi Analysis™, fabrication and fitting of the band and all follow-up and adjustment appointments. Approximately 20% of our patients are treated with a second band in order to achieve the desired correction. To gauge the need for an additional band, there are a number of factors to take into consideration, including the severity and complexity of the head shape, as well as the age and growth of the infant. If a second band is required, the full cost of treatment with a second band will be re-incurred.

DISCLAIMER
Informed consent documents are used to communicate information about the proposed treatment of a condition along with disclosure of risks and alternative forms of treatment. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your referring physician may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Results of the DOC Band may vary with each case, regardless of compliance, and may not always produce complete correction into full symmetry. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

Cranial Technologies, Inc. and/or your insurance provider will not be liable for damage that occurs to the product if proper wear & care protocols are not followed, or if the product is lost or damaged.

Please note: It is important that you read the above information carefully and have all of your questions answered before signing the consent.

Patient Bill of Rights

- *To be treated with dignity, respect and consideration*
- *To have your medical records kept confidential*
- *To have every consideration of privacy related to your medical care*
- *To refuse to participate in any research*
- *To refuse treatment*
- *To receive the information you need to make an informed decision about your child's health*
- *To receive information in terms and language you can understand*

Concerns or complaints can be addressed to:

Patient Relations Coordinator
1395 W. Auto Drive
Tempe, AZ 85284
866-DOC-BAND

I have read and have been given the opportunity to ask questions regarding treatment with the DOC Band and I understand the risks involved with use of the DOC Band.

_____	_____	_____
Parent or Legal Guardian	Patient Name	Date

Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Uses and Disclosures of Protected Health Information

Treatment: Your health information may be used by Cranial Technologies, Inc. staff members or disclosed to other health care professionals for the purpose of evaluating your health, diagnosing medical conditions, and providing treatment. For example, results of laboratory tests and procedures will be available in your medical record to all health professionals who may provide treatment or who may be consulted by staff members.

Payment: Your health information may be used to seek payment from your health plan or from credit card companies you may use to pay for services. For example, your health plan may request and receive information on dates of service, the services provided, and the medical condition being treated.

Health Care Operation: Your health information may be used as necessary to support day-to-day activities and management of Cranial Technologies, Inc. For example, information on the services you received may be used to support budgeting and financial reporting, and activities to evaluate and promote quality.

Health Oversight Activities: We may disclose your health information to a health oversight agency that ensures that Cranial Technologies is complying with the rules of government programs such as Medicaid.

Individuals Involved in Care or Payment for Care: We may use and disclose your health information in some situations where you have the opportunity to agree or object to certain uses and disclosures. For example, we may disclose your health information to a family member, friend or other person to the extent necessary to help with your health care.

Judicial and Administrative Proceedings: We may disclose your health information in the course of a judicial or administrative proceeding if we receive a legal order or other lawful process requiring us to disclose your health information.

Law Enforcement: Your health information may be disclosed to law enforcement agencies to support government audits and inspections, to facilitate law-enforcement investigations, and to comply with government-mandated reporting.

Health and Safety: We may disclose your health information if we reasonably believe that disclosure would prevent or lessen a serious or imminent threat to a person's or the public's health or safety. This applies to suspected victims of abuse, neglect or exploitation.

Public Health Reporting: Your health information may be disclosed to public health agencies as required by law. For example, we are required to report certain communicable diseases to the State's public health department.

Other Uses and Disclosures Require Your Authorization: Disclosure of your health information or its use for any purpose other than those listed above requires your written authorization. If you change your mind after authorizing a use or disclosure of your information you may submit a written revocation of the authorization. However, your decision to revoke the authorization will not affect or undo any use or disclosure of information that occurred before you notified us of your decision to revoke your authorization.

Additional Uses of Information: We may contact you to remind you of appointments and to provide you with information about treatment alternatives that you may find interesting or other health-related benefits and services that may be of interest to you.

Duties of Cranial Technologies, Inc.: We are required by law to maintain the privacy of your protected health information and to provide you with this notice of privacy practices. We are required to abide by the privacy policies and practices outlined in this notice. We are required to notify you, and the Department of Health and Human Services, if there is a breach of unsecured Protected Health Information.

Rights to Revise Privacy Practices: As permitted by law, we reserve the right to amend or modify our privacy policies and practices. These revisions in our policies and practices may be required by changes in federal or state laws and regulations. Upon request, we will provide you with the most recently revised notice on any office visit. The revised policies and practices will be applied to all protected health information we maintain.

Notice of Privacy Practices

Individual Rights
You have certain rights under the federal privacy standards. These include:

- The right to restrict disclosures to insurers if services are paid in full out of pocket.
- The right to request restrictions on the use and disclosure of your protected health information.
- The right to receive confidential communications concerning your medical condition and treatment by an alternate means or at alternative locations.
- The right to inspect and copy your protected health information.
- The right to amend or submit corrections to your protected health information.
- The right to receive an accounting of how and to whom your protected health information has been disclosed.
- The right to receive a printed copy of this notice.
- The right to receive an electronic copy of electronic health information.

Requests to Inspect Protected Health Information: You may generally inspect or copy the protected health information that we maintain. As permitted by federal regulation, we require that requests to inspect or copy protected health information be submitted in writing. You may obtain a form to request access to your records by contacting the Cranial Technologies' Patient Coordinator. Your request will be reviewed and will generally be approved unless there are legal or medical reasons to deny the request.

Complaints: If you would like to submit a comment or complaint about our privacy practices, you may do so by sending a letter outlining your concerns to:

HIPAA Privacy Official
Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, AZ 85284-1026

If you believe that your privacy rights have been violated, you should call the matter to our attention by sending a letter describing the cause of your concern to the same address. You may also file written complaints with the Secretary of the U.S. Department of Health and Human Services. Upon request, we will provide you with the address for the Secretary. You will not be penalized or otherwise retaliated against for filing a complaint.

Contact Person:
The name and address of the person you may contact for further information concerning our privacy practices is:

HIPAA Privacy Official
Cranial Technologies, Inc.
1395 West Auto Drive
Tempe, AZ 85284-1026
480-505-1840 ex 230

Effective Date:
This notice is effective on or after 11-01-2013

I have received the Notice of Privacy Practices from Cranial Technologies, Inc.

Signature of Patient and/or Patient Representative Date

Authorization for Use or Disclosure for Marketing and Publication

Name of Company: Cranial Technologies, Inc.
Address: 1395 W. Auto Drive Tempe AZ 85284
Privacy Official: Tammy Jones
Telephone: 866-362-2263

Patient Name: _____
[print or type]

I hereby authorize the use and disclosure of individually identifiable health information relating to the patient listed above as described below:

Specific description of the information to be used or disclosed:

Clinical data, DSi® imaging and photography created and/or collected at the clinic during the treatment process.
The above information will be called "Authorized Information" throughout the rest of this form.

Persons or class of persons authorized to make the use or disclosure of authorized information: *Cranial Technologies, Inc.*

- I understand that such photographs or DSi imaging may be published by various journals in any print, visual or electronic media, specifically including, but not limited to, medical journals and textbooks, for the purpose of informing the medical profession or the general public about plagiocephaly. Neither I nor any member of my family, will be identified by name in any publication. I understand that in some circumstances the photographs may portray features, which shall make the patient's identity recognizable.

- I understand that such photographs or DSi imaging may be used on the web site or social media channels of Cranial Technologies, Inc .

- I understand that I may revoke this authorization at any time by notifying Cranial Technologies, Inc. in writing. However, if I choose to do so, I understand that my revocation will not affect any actions taken by Cranial Technologies, Inc. before receiving my revocation.

- I understand that I may refuse to sign this authorization and that my refusal to sign in no way affects my treatment, payment, or eligibility for benefits.

- I understand that Cranial Technologies, Inc. may require me to sign an authorization prior to receiving research-related treatment or treatment solely for the purpose of creating health information for another party and that Cranial Technologies, Inc. will not provide such research-related treatment unless I provide this authorization.

- I understand that the person or entity I am authorizing to use and/or disclose Authorized Information for marketing purposes may receive either direct or indirect compensation for doing so.

- I understand that the information disclosed, or some portion thereof, may be protected by state law and/or HIPAA. I further understand that, because the entity receiving the information is not a health care provider or health plan covered by HIPAA, may re-disclose the information. I release and discharge Cranial Technologies, Inc. and all parties acting under their license from any claim that I may have relating to such use in publication, including any claim for payment in connection with distribution or publication of the photographs.

Signature of Patient or Patient's Personal Representative: _____

Date: _____